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Abstract

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A Clinical Comparison of Two Gas Permeable Contact Lenses (GPII and PolyconII) with Respect to Corneal Edema

A Thesis Presented to the
Faculty of the Pacific
University College of Optometry
in Partial Fulfillment of
the Requirements for the
Doctor of Optometry Degree

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Mitchell D. Harstad
Faculty Advisor, Don C. West O.D.

March 1984

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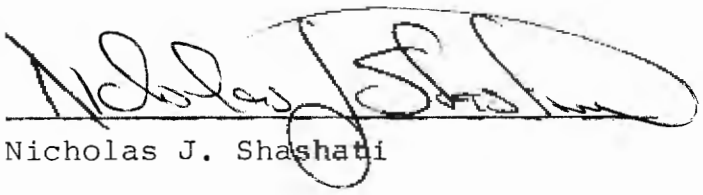

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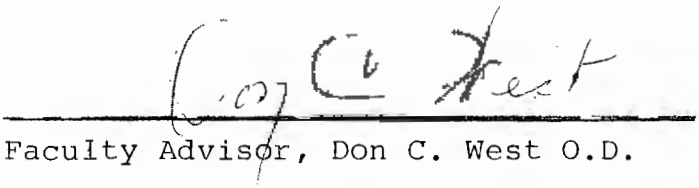

Faculty Advisor, Don C. West O.D.

March 1984

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The experimentors would also like to thank Ron O'Hara of Barnes-Hind/Hydrocurve and George Frick of Syntex Ophthalmics, Inc. for their cooperation in providing the complimentary lenses (GPII and PolyconII) for the subjects in this study.

Abstract

Corneal edema was assessed for two gas permeable lenses (GPII and PolyconII) on five locations across the horizontal meridian. Each of these lenses have received FDA approval and are made of PMMA-Silicone polymer and Cellulose acetate butyrate respectively.

Sixteen subjects were randomly selected who showed no contra-indications to contact lens wear and were fitted using standard contact lens fitting criteria with slight apical clearance and no marked peripheral seal-off.

These subjects were observed while wearing both PolyconII and GPII, using a contralateral eye study protocol, for a period of 28 days. Pachometry was used to monitor changes in corneal thickness.

There was no significant difference in the amount of swelling from baseline for these two lenses across five horizontal corneal locations; as well as, no significant difference using a 98% confidence level when compared one lens to the other. Nonstatistically, a general trend was observed for most all horizontal meridian with both lenses; a decrease in corneal thickness from baseline at day 7, then a marked increase at day 14, some even larger than baseline, and finally, a corneal thinning at day 28 below baseline values.

Introduction

Until recent years, Polymethyl methacrylate (PMMA) lenses have exclusively been the lens of choice for hard contact lens wearers. The major problem though adapting to PMMA was the constant occurance of corneal edema due to inadequate supply of oxygen to the corneal surface.

The cornea generally receives its oxygen supply from three major sources: the aqueous, the limbal vessels, and the atmosphere via the tear layer. It is believed that the endothelium and posterior stroma are supplied by the aqueous whereas the epithelium is supplied by the tear layer.[1]

Based on an experiment by Hill, the oxygen tension present at the corneal surface of an open eye expressed in "equivalent oxygen percentage" (E.O.P.) is approximately 21 percent. Hence 21 percent of the total available pressure exerted on the earth by the atmosphere at sea level (760 mm Hg) is approximately 155 mm Hg.[2]

In 1970, Polse and Mandell have shown that only 11.4 to 19.0 mm Hg of that 155 mm Hg was sufficient to prevent corneal edema. In E.O.P., that figure equals two to five percent of the available atmospheric oxygen needed to satisfy the minimal corneal oxygen demand.[3]

In 1980, through better experimentation and reliability, Mandell and Farrell demonstrated that higher thresholds, a significant difference in the minimum oxygen was required for individuals. The average value was noted to be at least 23 mm Hg and varied dependently on the individual characteristics.[4]

In 1982, Weissman declared that corneal swelling began when oxygen tension decreased to a value below 3 to 5 percent or 20 to 35 mm Hg. [5]

Most recent update from the Contact Lens Update Journal in 1983, experimenting with hard gas permeable lenses as extended wear, declared that the minimum oxygen tension to prevent lens induced corneal edema during sleep in 40 to 50 mm Hg or E.O.P. value of 5 to 6.5 percent.[6]

Since the PMMA polymer transmits very little oxygen[7], the major supply of oxygen to the corneal surface was tear pump dependent. Since this only constitutes 1 to 3 percent oxygen, then a significant proportion of the contact lens wearing population would have had partial oxygen deficit and be labelled as "edema prone".[8,9] The amount of corneal swelling is author specific and ranged between 2 to 10 percent averaging about 6.65 percent.[4,5,10] Other characteristic changes that also resulted from long term PMMA wear included; central corneal clouding[11,12], edematous corneal formation[13], spectacle blur[14], and refractive and corneal curvature changes[15,16], all bi-products of corneal swelling.

It is then established that the tear pump mechanism alone was not sufficient to provide the adequate oxygen demand needed to prevent hypoxia; hence, a new contact lens material was in order and gas permeable lenses came into play. Gas permeable lenses supply oxygen to the cornea, not only by means of a tear pump mechanism, but also by direct transmission through the lens material itself.

In 1977, Sarver and others reported 46 patients who experienced failure with PMMA due to excessive edema, but when refitted with PMMA/Siloxane lenses, no significant edema was observed.[17]

Further, a study in 1979 by Sarver, Brown and Riggest assessing corneal edema with several hard corneal contact lenses including; PMMA, BP Flex, and Polycon, showed that the amount of edema developed by patient wearing BP Flex was not significantly different than the edema developed by patient wearing PMMA lenses of the same dimensions. Yet, Polycon wear patients developed less corneal edema than either of the above lenses.[18]

Also in 1977, Hill suggested that Cellulose Acetate Butyrate (C.A.B.) lenses with center thickness of less than 0.15 mm could prevent pachometrically detectable edema (1.5 to 2.0%).[5,19]

In 1979, Millodot et al demonstrated an increase of central corneal thickness of 3 percent associated with PMMA lenses versus a 1 percent increase with C.A.B. lenses.[20]

Eschman reported that out of 260 eyes (196 fitted with C.A.B. from beginning and 64 refitted with C.A.B. after worn PMMA) only 5 out of the 196 showed mild edema, and 8 out of the 64 were not satisfactory with the refit. In essence, patient adapted relatively quick and easy with the C.A.B. lenses and edema was much less pronounced.[21]

In 1980, Finnemore and Korb demonstrated that corneal edema was present after four hours of wearing PMMA lenses in 192 of 200 corneas (96%) tested, and in 171(85%) the edema was rated as clinically significant (grade one or higher). With the Polycon lenses wearers, only 32 eyes (16%) exhibited some degrees of edema after four hours of wear, of which 12 cases (6%) were deemed clinically significant.[22]

In 1981, Lowther compared the changes in corneal thickness using Silcon Resin Lenses to the changes using PMMA, C.A.B., and Polycon lenses. It was found that the eyes with the PMMA lenses had significantly more edema than those with the silicon lenses. And with the patients wearing C.A.B. or Polycon as compared to silcon, there was substantially less swelling the first week of wear with the silcon lenses, but hence after, no swelling differences were observed between these three lenses.[23]

Finally in 1983, Bennett and Tomlinson supported the claims made by manufacturers of gas permeable hard lenses (Polycon) that immediate refitting with these lenses reduced corneal edema and provides an adequate correction to long term PMMA wearers without inhibiting the changes which take place after the removal of the original lenses.[24]

It is then established that different gas permeable hard lens materials behave differently, mostly due to their differences in oxygen transmissibility, permeability, and wetting angle.

The purpose then of this study is to investigate how two such lenses behave with respect to corneal edema and physiology. More specifically, an attempt was made to answer the question: Is there a significant difference between these two gas permeable

lenses (PolyconII, Silafacon A, a Siloxane - PMMA product from Syntex Ophthalmics Inc., and GPII, profocon B, a cellulose acetate butyrate product from Barnes Hind Hydrocurve Inc.) in reducing corneal edema?

Methods

A group of 16 subjects, 4 of whom were female, were selected for participation in the study. They were chosen from a mixed population of previous hard, soft, or no contact lens experience. To be specific four were previous hard PMMA lens wearers, four were soft lens wearers, and eight were first time contact lens wearers. The subjects ranged from twelve to thirty-three years of age. Each participant was required to fulfill the depicted criteria set forth prior to experimentation: A corneal cylinder equal to or less than 1.50 diopters; no limitation on refractive astigmatism; and no known ocular or systemic pathological conditions including dry eye syndromes.

All subjects were fitted with the two different gas permeable lenses, one in each eye (right eye with PolyconII; left eye with GPII). Adequacy of lens fit was determined by the experimenters, using standard criteria as lens centering, movement, flourescein patterns, absence of epithelial abrasions, acuity with over-refraction, keratometry readings, pre and post-refractions, etc. A lens cornea relationship of slight apical clearance (lacrimal line to reference line equals 1.3 to 1) with no marked seal-off was desired.

Standard lens parameters employed from each manufacturer were maintained and used in the study. See Table 1.

Table 1 Lens Characteristics

Specification	Polycon/Silafocon A	GPII/Porofocon B
lens diameter	9.0 mm	9.2 mm
optic zone diameter	7.8 mm	7.6 mm
secondary curve width	0.40 mm	0.40 mm
peripheral curve width	0.20 mm	0.20 mm
blend width	M	0.20 mm
center thickness	.15 - .08 mm	0.18 mm
edge thickness	.08 - .12 mm	0.08 mm

Upon dispensing, all patients were instructed in the proper handling and care of the lenses. Alergan products were used for cleaning, storing, and wetting (LC65 for cleaning, Wet-n-Soak for wetting and soaking).

The wearing schedule prescribed for these gas permeable lenses is shown in Table 2.

Table 2 Wearing Schedule

Day	Hour
Dispensing day to day 7	4 hours/day
day 7 to day 14	6 hours/day
day 14 to day 28	full time wear

Level of corneal swelling or thickness was assessed using an Electronic Digital Computer Pachometer Mode 11 RD, marketed by Cooper Dicon Ophthalmic.[25,26] It is equipped with a series of fixation lights along the horizontal axis so that consistent central and peripheral measurements can be made. Corneal thickness was measured across five corneal locations along the horizontal (left extreme periphery, left mid periphery, central, right mid periphery, right extreme periphery). Although the lenses had to be removed for pachometry, every effort was made to keep the time between removal and measurement to a minimum.

Pachometry measurements were recorded over a period of four weeks, as shown in table 3.

Table 3 Schedule of measurements

Day of Measurement	Hours of Wear Prior to Measurements
Day 1	Baseline
Day 7	After 4 hours wear
Day 14	After 6 hours wear
Day 28	After 8 hours wear

Minor modification after day 7 was made due to patient symptomology. For poor wetting signs and symptoms, a surface polish procedure of both concave and convex sides of both lenses were done using a sponge tool, spinner, and LC65. For those patients who complained of edge sensation, a 16 mm brass tool with Duracel was used to roll the edge over of both lenses. A drum tool was then used to finalize the edge design.

Major modifications when indicated were performed at end of study. This included a polish blend series with X-Pal.[27] See Table 4 for blend procedure.

Table 4 Blend Procedure adapted from TABB

Steps	Tool	Time
Step 1	(Base curve + 1.0 mm) + (velveteen) + X-Pal	No longer than 2 sec.
Step 2	(BC + 1.5 mm) + velveteen + X-Pal	No longer than 2 sec.
Step 3	continue in 0.5 mm increments until PCR is reached	No longer then 2 sec. for each tool

Results

Changes in mean corneal thickness for all five locations across the horizontal meridian while wearing PolyconII are shown in tables 5a-5e, 6a-6e, 7a-7e. The previous tables listed describe subjects who were previous non-lens wearers, previous soft lens wearers, and previous hard lens wearers respectively. The tables show the average corneal thickness, standard deviation, and range measured at those five locations on the cornea over a period of twenty-eight days.

Overall thickness percentage changes from baseline to seven days, baseline to fourteen days, and baseline to twenty-eight days, as well as, their significant value using a 95% confidence level are also depicted in these tables. The mean corneal thickness values for all five locations of the cornea (nasal extreme periphery, nasal mid periphery, central, temporal mid periphery, temporal extreme periphery) showed no statistically significant increase over the three time measurement allowed: Baseline to 7 days, baseline to 14 days, baseline to 28 days (student's t test, $t > 0.05$).

Tables 8a-8e, 9a-9e, 10a-10e show the same information about corneal thickness, but with subjects wearing GPII lenses. Again in this case, no significant differences were observed at a 95% confidence level in increase corneal swelling for previous nonwearers, previous soft lens wearers, and previous hard lens wearers (student t-test $t > 0.05$).

Although these values indicate no significant differences in the level of corneal edema for each lens alone, it is worth while to investigate the general trend and similarities that do exist in these lenses at the different corneal locations.

Figure 1 graphically indicates the rate of increase for mean corneal thickness of previous non wear subjects now wearing PolyconII. It is of interest to note that central cornea thickness increased on a gradual level from baseline, then tapering at approximately .01 mm above baseline at end of 28 days; while other corneal locations showed a reducation of corneal

thickness, more pronounced at day 7, followed ultimately by a corneal thinning to below baseline levels at end of 28 days. Figure 2 graphically depicts the same results but with GPII except that even central cornea showed this reduction in corneal thickness at day 7. Figures 3a-3e graphically compare the percent change in corneal thickness from baseline in mean central, nasal mid periphery, nasal extreme periphery, temporal mid periphery and temporal extreme periphery for both PolyconII and GPII.

Figure 4 and 5 indicate same analysis as preceeding Figure 1 and 2 except with previous soft lens wear subjects. Again we notice this reduction in corneal thickness for all corneal locations across the horizontal, most marked at day 7. Figures 6a-6e again compare the percent change in corneal thickness from baseline for both PolyconII and GPII for all 5 corneal locations.

Finally, Figures 7 and 8, like Figures 1,2,4 and 5, indicate the corneal thickness change for both lenses for previous hard lens wear subjects. It is of interest that for both lenses in this group of subjects, central and temporal mid periphery corneal locations did not change thickness at day 7; thereafter increasing in thickness up to day 14, and finally show this reduction below baseline at day 28. All other locations carry the same trend as previously stated with slight variations. Figures 9a-9e compare the percent change in corneal thickness for both PolyconII and GPII lenses.

Tables 11a -11e and 12a-12e along with figures 10 and 11 represent the corneal thickness changes for both PolyconII and GPII for the five horizontal locations for all subjects combined. Again for slight variations, the trend indicates a corneal deswelling at day 7 below baseline, then swelling up to day 14, some even above baseline value, and lastly a final deswelling or reduction of corneal thickness to a value below baseline. Figures 12a-12e again compare the percent change in corneal thickness for both PolyconII and GPII lenses.

Tables 13a-c represent individual percent change in corneal thicknesses with PolyconII and GPII for all five corneal locations. Subjects 1 through 8 are previous non lens wearers; subjects 9 through 12 are previous hard lens wearers. The mean percentage decrease in central corneal thickness was -0.21 for PolyconII lens wearers and -2.43 for GPII for all subjects. Student t-test at 95% confidence level indicate that there is no significant difference between PolyconII and GPII in terms of corneal swelling. Same conclusion was reached for all other horizontal corneal locations. See tables 12b and 12c.

Point of interest, non-statistically, is that in Figure 11 and 12 when plotting individuals of previous non lens wearers, previous soft lens wearers and previous hard lens wearers for both PolyconII and GPII, one observes the negative percentage change or deswelling of cornea with previous hard lens wear as compared to the positive percentage change or swelling of cornea with previous non lens wear. Certain variations existed among some individuals, but overall, the trend was marked.

Discussion

An extensive statistical analysis was performed and its results prepared as a comparison between two recently developed gas permeable contact lenses (PolyconII/Syntex Ophthalmics, and GPII/Barnes Hind Hydrocurve). The study attempted to answer questions such as: Is there a significant increase in corneal edema wearing these gas permeable lenses and is there a difference between these two lenses with respect to minimize corneal swelling. The results indicated no significant corneal thickness change for all five horizontal corneal locations (nasal and temporal extreme peripheries, nasal and temporal mid peripheries, and central cornea) using a 95% confidence level.

The study also compared corneal thickness wearing these two gas permeable lenses with previous hard, soft and non contact lens wear subjects. Again, there was not statistical significant difference to indicate a reduction in corneal edema with these previous lens wearers. Although no significant differences were found with the previous hard lens wearers, probably due to the small sample size, a graphical presentation in Figure 13 and 14 show a reduction in corneal thickness for individuals with one exception.

It is of interest to note that for most corneal locations for both GPII and PolyconII lenses, a reduction in corneal swelling is observed at day 7 then a surge in thickness present at day 14 to a value at times above baseline, and finally a re-reduction to a value lower than baseline at day 28. This is graphically represented on Figures 1,2,4,5,7,8,10 and 11. A summary schematic diagram is shown below representing the trend observed. See Figure 15.

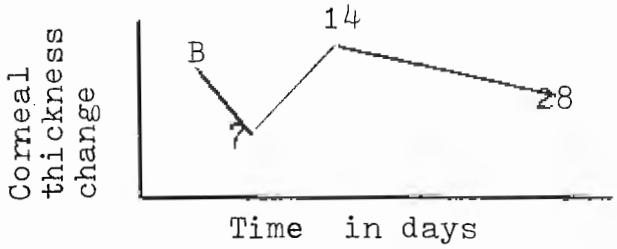


Figure 15
Summary graph representing trend observed for corneal thickness for Polycon II & GP II.

Although the data compiled was suggestive of several other areas of interest that would be tempting to investigate further, the investigators have made an effort to limit the scope of this study to considerations that appear to be directly related to corneal edema.

However, it is helpful to point out further more lens characteristics that would be applicable in this study. Oxygen permeability of a lens material is expressed in terms of the co-efficient of gas permeability (DK value) - the product of the diffusion co-efficient (D) and the solubility co-efficient(K). More precisely, oxygen permeability should be expressed in terms of DK/L (L= center thickness of lens). Such values for both these lenses are shown on Table 14.

Table 14 Oxygen Permeability Values for PolyconII and GPII

	DK	DK/L
PolyconII	12×10^{-11}	12×10^{-10} (Assuming center thickness average of 0.10 mm)
GPII	9.2×10^{-11}	5.1×10^{-10} (Assuming center thickness value of 0.18 mm)

Since (L) varies in DK/L for PolyconII lenses due to different center thicknesses attributing to differnet minus powers, the DK/L value will also vary; however, for all center thickness values noted in Table 1 for Polycon, the DK/L is still higher for PolyconII than GPII. GPII lenses maintain a standard thickness of 0.18 mm for all minus lenses to minimize lens flexure.

Wetting angle is also of significance when discussing patient comfort due to lens dryness. PolyconII obtains a wetting angle of 15° , whereas, GPII enjoys a 13.5° wetting angle - indicating that the latter would be more efficient in preventing lens dryness while on the eye. However, clinically for this study, subjective symptoms for both lenses indicated a front and back surface polish procedure, as explained in methodology to enhance

lens wetting ability and patient comfort. Polished blend series were also performed for compliance of patient comfort.

In summary, we have seen that no significant difference exists in both GPII and PolyconII lenses to minimize corneal edema across all horizontal corneal meridians. We have also seen non-statistically, that a reduction of corneal thickness exists for the meridian tested to a value below baseline at day 7, then reswelling at day 14 and finally a last reduction at day 28 - resulting in corneal thinning to a value below baseline levels. This trend towards corneal thinning with highly permeable materials has been reputed previously by others. The mechanism is still unclear and further investigation is needed to explore this phenomenon.

Some modifications of the experimental procedure should be considered. First, a larger sample size for each group category is indicated. This would enhance the significance of the statistical analysis. Second, although maximum effort was made to minimize time allowance between lens removal and pachometry measurement, a more sophisticated approach could be indicated.

TABLE 5a

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS NON CONTACT LENS WEAR SUBJECTS

CENTRAL

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.545	0.014	0.518-0.566
AFTER 7 DAYS WEAR	0.547	0.043	0.501-0.616
AFTER 14 DAYS WEAR	0.556	0.043	0.500-0.601
AFTER 28 DAYS WEAR	0.555	0.048	0.495-0.609

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	+0.37
BASELINE TO 14 DAYS	+2.02
BASELINE TO 28 DAYS	+1.83

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 5b

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS NON CONTACT LENS WEAR SUBJECTS

NASAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.579	0.036	0.507-0.634
AFTER 7 DAYS WEAR	0.565	0.053	0.501-0.639
AFTER 14 DAYS WEAR	0.595	0.061	0.524-0.682
AFTER 28 DAYS WEAR	0.572	0.060	0.498-0.636

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-2.42
BASELINE TO 14 DAYS	+2.76
BASELINE TO 28 DAYS	-1.21

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 5c

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS NON CONTACT LENS WEAR SUBJECTS

NASAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.642	0.063	0.521-0.745
AFTER 7 DAYS WEAR	0.627	0.062	0.528-0.697
AFTER 14 DAYS WEAR	0.652	0.053	0.599-0.719
AFTER 28 DAYS WEAR	0.643	0.074	0.529-0.723

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-2.34
BASELINE TO 14 DAYS	+1.56
BASELINE TO 28 DAYS	+0.16

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 5d

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS NON CONTACT LENS WEAR SUBJECTS

TEMPORAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.569	0.030	0.521-0.624
AFTER 7 DAYS WEAR	0.563	0.048	0.508-0.625
AFTER 14 DAYS WEAR	0.566	0.037	0.507-0.610
AFTER 28 DAYS WEAR	0.599	0.049	0.500-0.613

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.05
BASELINE TO 14 DAYS	-0.53
BASELINE TO 28 DAYS	-1.76

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant t>0.05
BASELINE TO 14 DAYS	not significant t>0.05
BASELINE TO 28 DAYS	not significant t>0.05

TABLE 5c

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS NON CONTACT LENS WEAR SUBJECTS

TEMPORAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.612	0.038	0.558-0.670
AFTER 7 DAYS WEAR	0.592	0.058	0.525-0.684
AFTER 14 DAYS WEAR	0.601	0.047	0.541-0.658
AFTER 28 DAYS WEAR	0.601	0.052	0.577-0.656

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-3.27
BASELINE TO 14 DAYS	-1.80
BASELINE TO 28 DAYS	-1.80

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 6a

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS SOFT CONTACT LENS WEAR SUBJECTS

CENTRAL

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.523	0.019	0.505-0.545
AFTER 7 DAYS WEAR	0.529	0.033	0.501-0.571
AFTER 14 DAYS WEAR	0.545	0.039	0.511-0.599
AFTER 28 DAYS WEAR	0.523	0.023	0.500-0.541

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-0.75
BASELINE TO 14 DAYS	+2.25
BASELINE TO 28 DAYS	-1.88

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t > 0.05$
BASELINE TO 14 DAYS	not significant $t > 0.05$
BASELINE TO 28 DAYS	not significant $t > 0.05$

TABLE 6b

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS SOFT CONTACT LENS WEAR SUBJECTS

NASAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.565	0.026	0.531-0.593
AFTER 7 DAYS WEAR	0.554	0.049	0.506-0.614
AFTER 14 DAYS WEAR	0.569	0.054	0.527-0.643
AFTER 28 DAYS WEAR	0.546	0.022	0.520-0.569

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.95
BASELINE TO 14 DAYS	+0.71
BASELINE TO 28 DAYS	-3.36

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 6c

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS SOFT CONTACT LENS WEAR SUBJECTS

NASAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.660	0.050	0.591-0.698
AFTER 7 DAYS WEAR	0.612	0.059	0.550-0.664
AFTER 14 DAYS WEAR	0.654	0.074	0.585-0.735
AFTER 28 DAYS WEAR	0.637	0.056	0.582-0.699

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-7.27
BASELINE TO 14 DAYS	-0.91
BASELINE TO 28 DAYS	-3.48

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 6d

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS SOFT CONTACT LENS WEAR SUBJECTS

TEMPORAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.539	0.024	0.508-0.564
AFTER 7 DAYS WEAR	0.531	0.036	0.500-0.574
AFTER 14 DAYS WEAR	0.550	0.035	0.519-0.566
AFTER 28 DAYS WEAR	0.541	0.028	0.504-0.566

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.48
BASELINE TO 14 DAYS	+2.04
BASELINE TO 28 DAYS	+0.37

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t > 0.05$
BASELINE TO 14 DAYS	not significant $t > 0.05$
BASELINE TO 28 DAYS	not significant $t > 0.05$

TABLE 6e

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS SOFT CONTACT LENS SUBJECTS

TEMPORAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.590	0.045	0.536-0.631
AFTER 7 DAYS WEAR	0.576	0.024	0.552-0.594
AFTER 14 DAYS WEAR	0.588	0.034	0.551-0.604
AFTER 28 DAYS WEAR	0.579	0.025	0.556-0.604

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-2.37
BASELINE TO 14 DAYS	-0.34
BASELINE TO 28 DAYS	-1.86

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant t>0.05
BASELINE TO 14 DAYS	not significant t>0.05
BASELINE TO 28 DAYS	not significant t>0.05

TABLE 7a

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS HARD CONTACT LENS WEAR SUBJECTS

CENTRAL

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.540	0.043	0.501-0.601
AFTER 7 DAYS WEAR	0.540	0.076	0.492-0.653
AFTER 14 DAYS WEAR	0.541	0.052	0.511-0.619
AFTER 28 DAYS WEAR	0.525	0.051	0.489-0.600

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	0.00
BASELINE TO 14 DAYS	+0.19
BASELINE TO 28 DAYS	-2.78

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 7b

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS HARD CONTACT LENS WEAR SUBJECTS

NASAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.578	0.058	0.528-0.661
AFTER 7 DAYS WEAR	0.572	0.084	0.527-0.697
AFTER 14 DAYS WEAR	0.561	0.066	0.523-0.636
AFTER 28 DAYS WEAR	0.556	0.054	0.523-0.636

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.04
BASELINE TO 14 DAYS	-2.94
BASELINE TO 28 DAYS	-3.81

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant t>0.05
BASELINE TO 14 DAYS	not significant t>0.05
BASELINE TO 28 DAYS	not significant t>0.05

TABLE 7c

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS HARD CONTACT LENS WEAR SUBJECTS

NASAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.662	0.081	0.602-0.781
AFTER 7 DAYS WEAR	0.637	0.107	0.576-0.797
AFTER 14 DAYS WEAR	0.648	0.102	0.590-0.801
AFTER 28 DAYS WEAR	0.626	0.100	0.559-0.774

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-3.78
BASELINE TO 14 DAYS	-2.11
BASELINE TO 28 DAYS	-5.44

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t > 0.05$
BASELINE TO 14 DAYS	not significant $t > 0.05$
BASELINE TO 28 DAYS	not significant $t > 0.05$

TABLE 7d

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS HARD WEAR CONTACT LENS WEAR SUBJECTS

TEMPORAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.549	0.043	0.517-0.611
AFTER 7 DAYS WEAR	0.552	0.073	0.503-0.660
AFTER 14 DAYS WEAR	0.553	0.061	0.510-0.643
AFTER 28 DAYS WEAR	0.527	0.049	0.487-0.592

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	+0.55
BASELINE TO 14 DAYS	+0.73
BASELINE TO 28 DAYS	-4.01

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 7e

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR PREVIOUS HARD CONTACT LENS WEAR SUBJECTS

TEMPORAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.591	0.047	0.550-0.655
AFTER 7 DAYS WEAR	0.573	0.066	0.536-0.671
AFTER 14 DAYS WEAR	0.599	0.080	0.548-0.718
AFTER 28 DAYS WEAR	0.570	0.073	0.519-0.676

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-2.37
BASELINE TO 14 DAYS	+1.35
BASELINE TO 28 DAYS	-3.55

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 8a

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS NON CONTACT LENS WEAR SUBJECTS

CENTRAL

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.561	0.026	0.515-0.594
AFTER 7 DAYS WEAR	0.544	0.029	0.501-0.574
AFTER 14 DAYS WEAR	0.547	0.038	0.497-0.585
AFTER 28 DAYS WEAR	0.544	0.040	0.496-0.586

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-3.03
BASELINE TO 14 DAYS	-2.50
BASELINE TO 28 DAYS	-3.03

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t > 0.05$
BASELINE TO 14 DAYS	not significant $t > 0.05$
BASELINE TO 28 DAYS	not significant $t > 0.05$

TABLE 8b

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS NON CONTACT LENS WEAR SUBJECTS

NASAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.569	0.041	0.513-0.625
AFTER 7 DAYS WEAR	0.567	0.052	0.515-0.633
AFTER 14 DAYS WEAR	0.570	0.037	0.510-0.619
AFTER 28 DAYS WEAR	0.564	0.048	0.498-0.619

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-0.35
BASELINE TO 14 DAYS	+0.18
BASELINE TO 28 DAYS	-0.88

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t > 0.05$
BASELINE TO 14 DAYS	not significant $t > 0.05$
BASELINE TO 28 DAYS	not significant $t > 0.05$

TABLE 8c

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS NON CONTACT LENS WEAR SUBJECTS

NASAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.624	0.050	0.570-0.720
AFTER 7 DAYS WEAR	0.626	0.068	0.537-0.719
AFTER 14 DAYS WEAR	0.621	0.051	0.559-0.677
AFTER 28 DAYS WEAR	0.619	0.053	0.555-0.678

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	+0.32
BASELINE TO 14 DAYS	-0.48
BASELINE TO 28 DAYS	-0.80

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 8d

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS NON CONTACT LENS WEAR SUBJECTS

TEMPORAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.572	0.036	0.519-0.621
AFTER 7 DAYS WEAR	0.561	0.040	0.516-0.627
AFTER 14 DAYS WEAR	0.566	0.046	0.511-0.632
AFTER 28 DAYS WEAR	0.564	0.040	0.500-0.594

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.92
BASELINE TO 14 DAYS	-1.05
BASELINE TO 28 DAYS	-1.40

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 8e

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS NON CONTACT LENS WEAR SUBJECTS

TEMPORAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.616	0.040	0.534-0.660
AFTER 7 DAYS WEAR	0.611	0.061	0.526-0.710
AFTER 14 DAYS WEAR	0.613	0.048	0.548-0.682
AFTER 28 DAYS WEAR	0.605	0.053	0.544-0.664

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-0.81
BASELINE TO 14 DAYS	-0.49
BASELINE TO 28 DAYS	-1.79

t TEST	RESULTS	
BASELINE TO 7 DAYS	not significant	$t > 0.05$
BASELINE TO 14 DAYS	not significant	$t > 0.05$
BASELINE TO 28 DAYS	not significant	$t > 0.05$

TABLE 9a

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS SOFT CONTACT LENS WEAR SUBJECTS

CENTRAL

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.541	0.022	0.516-0.569
AFTER 7 DAYS WEAR	0.535	0.035	0.506-0.580
AFTER 14 DAYS WEAR	0.548	0.047	0.514-0.616
AFTER 28 DAYS WEAR	0.536	0.027	0.512-0.573

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.11
BASELINE TO 14 DAYS	+1.29
BASELINE TO 28 DAYS	-0.92

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 9b

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS SOFT CONTACT LENS WEAR SUBJECTS

NASAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.553	0.017	0.532-0.569
AFTER 7 DAYS WEAR	0.548	0.041	0.511-0.597
AFTER 14 DAYS WEAR	0.559	0.050	0.512-0.625
AFTER 28 DAYS WEAR	0.556	0.059	0.504-0.620

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-0.90
BASELINE TO 14 DAYS	+1.08
BASELINE TO 28 DAYS	+0.54

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t > 0.05$
BASELINE TO 14 DAYS	not significant $t > 0.05$
BASELINE TO 28 DAYS	not significant $t > 0.05$

TABLE 9c

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS SOFT CONTACT LENS WEAR SUBJECTS

NASAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.620	0.034	0.590-0.650
AFTER 7 DAYS WEAR	0.620	0.078	0.551-0.694
AFTER 14 DAYS WEAR	0.646	0.071	0.579-0.729
AFTER 28 DAYS WEAR	0.617	0.057	0.560-0.669

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	0.00
BASELINE TO 14 DAYS	+4.19
BASELINE TO 28 DAYS	-0.49

t TEST	RESULTS	
BASELINE TO 7 DAYS	not significant	$t > 0.05$
BASELINE TO 14 DAYS	not significant	$t > 0.05$
BASELINE TO 28 DAYS	not significant	$t > 0.05$

TABLE 9d

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS SOFT CONTACT LENS WEAR SUBJECTS

TEMPORAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.558	0.015	0.546-0.579
AFTER 7 DAYS WEAR	0.555	0.034	0.516-0.594
AFTER 14 DAYS WEAR	0.559	0.042	0.519-0.612
AFTER 28 DAYS WEAR	0.544	0.035	0.508-0.578

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-0.54
BASELINE TO 14 DAYS	+0.18
BASELINE TO 28 DAYS	-2.51

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 9e

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS SOFT CONTACT LENS WEAR SUBJECTS

TEMPORAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.610	0.027	0.590-0.648
AFTER 7 DAYS WEAR	0.580	0.032	0.554-0.625
AFTER 14 DAYS WEAR	0.612	0.042	0.574-0.655
AFTER 28 DAYS WEAR	0.589	0.034	0.560-0.623

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-4.92
BASELINE TO 14 DAYS	+0.33
BASELINE TO 28 DAYS	-3.44

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 10a

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS HARD CONTACT LENS WEAR SUBJECTS

CENTRAL

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.540	0.037	0.506-0.591
AFTER 7 DAYS WEAR	0.540	0.070	0.501-0.645
AFTER 14 DAYS WEAR	0.555	0.071	0.518-0.661
AFTER 28 DAYS WEAR	0.524	0.047	0.488-0.591

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	0.00
BASELINE TO 14 DAYS	+2.78
BASELINE TO 28 DAYS	-2.96

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 10b

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS HARD CONTACT LENS WEAR SUBJECTS

NASAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.558	0.048	0.510-0.618
AFTER 7 DAYS WEAR	0.551	0.076	0.511-0.665
AFTER 14 DAYS WEAR	0.569	0.086	0.525-0.695
AFTER 28 DAYS WEAR	0.545	0.046	0.492-0.597

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.25
BASELINE TO 14 DAYS	+1.97
BASELINE TO 28 DAYS	-2.33

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 10c

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS HARD CONTACT LENS WEAR SUBJECTS

NASAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.628	0.045	0.582-0.689
AFTER 7 DAYS WEAR	0.612	0.078	0.568-0.729
AFTER 14 DAYS WEAR	0.630	0.094	0.567-0.769
AFTER 28 DAYS WEAR	0.601	0.055	0.568-0.679

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-2.23
BASELINE TO 14 DAYS	+0.32
BASELINE TO 28 DAYS	-4.30

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 10d

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS HARD CONTACT LENS WEAR SUBJECTS

TEMPORAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.555	0.043	0.528-0.619
AFTER 7 DAYS WEAR	0.553	0.070	0.508-0.657
AFTER 14 DAYS WEAR	0.552	0.053	0.520-0.631
AFTER 28 DAYS WEAR	0.527	0.048	0.492-0.596

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-0.36
BASELINE TO 14 DAYS	-0.54
BASELINE TO 28 DAYS	-5.05

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 10e

CORNEAL THICKNESS CHANGE WITH GP II FOR PREVIOUS HARD CONTACT LENS WEAR SUBJECTS

TEMPORAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.602	0.054	0.556-0.678
AFTER 7 DAYS WEAR	0.599	0.070	0.525-0.694
AFTER 14 DAYS WEAR	0.601	0.051	0.567-0.677
AFTER 28 DAYS WEAR	0.571	0.063	0.522-0.658

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-0.50
BASELINE TO 14 DAYS	-0.17
BASELINE TO 28 DAYS	-5.15

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 11a

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR ALL SUBJECTS

CENTRAL

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.540	0.040	0.501-0.601
AFTER 7 DAYS WEAR	0.541	0.048	0.492-0.653
AFTER 14 DAYS WEAR	0.549	0.034	0.500-0.619
AFTER 28 DAYS WEAR	0.539	0.044	0.485-0.609

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	+0.19
BASELINE TO 14 DAYS	+1.67
BASELINE TO 28 DAYS	-0.17

t TEST	RESULTS	
BASELINE TO 7 DAYS	not significant	$t>0.05$
BASELINE TO 14 DAYS	not significant	$t>0.05$
BASELINE TO 28 DAYS	not significant	$t>0.05$

TABLE 11b

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR ALL SUBJECTS

NASAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.575	0.038	0.507-0.661
AFTER 7 DAYS WEAR	0.564	0.057	0.501-0.697
AFTER 14 DAYS WEAR	0.580	0.058	0.523-0.682
AFTER 28 DAYS WEAR	0.561	0.049	0.498-0.636

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.91
BASELINE TO 14 DAYS	+0.87
BASELINE TO 28 DAYS	-2.43

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t > 0.05$
BASELINE TO 14 DAYS	not significant $t > 0.05$
BASELINE TO 28 DAYS	not significant $t > 0.05$

TABLE 11c

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR ALL SUBJECTS

NASAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.652	0.061	0.521-0.781
AFTER 7 DAYS WEAR	0.626	0.070	0.520-0.797
AFTER 14 DAYS WEAR	0.652	0.067	0.561-0.801
AFTER 28 DAYS WEAR	0.637	0.073	0.529-0.774

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-3.99
BASELINE TO 14 DAYS	0.00
BASELINE TO 28 DAYS	-2.30

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 11d

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR ALL SUBJECTS

TEMPORAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.557	0.033	0.505-0.624
AFTER 7 DAYS WEAR	0.552	0.051	0.500-0.660
AFTER 14 DAYS WEAR	0.559	0.068	0.507-0.643
AFTER 28 DAYS WEAR	0.547	0.044	0.487-0.613

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	+0.90
BASELINE TO 14 DAYS	+0.36
BASELINE TO 28 DAYS	-1.80

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 11e

CORNEAL THICKNESS CHANGE WITH POLYCON II FOR ALL SUBJECTS

TEMPORAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.601	0.036	0.536-0.670
AFTER 7 DAYS WEAR	0.583	0.051	0.525-0.684
AFTER 14 DAYS WEAR	0.597	0.051	0.541-0.718
AFTER 28 DAYS WEAR	0.588	0.051	0.519-0.676

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-3.00
BASELINE TO 14 DAYS	-0.67
BASELINE TO 28 DAYS	-2.16

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 12a

CORNEAL THICKNESS CHANGE WITH GP II FOR ALL SUBJECTS

CENTRAL

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.550	0.028	0.506-0.594
AFTER 7 DAYS WEAR	0.541	0.040	0.501-0.604
AFTER 14 DAYS WEAR	0.549	0.046	0.497-0.667
AFTER 28 DAYS WEAR	0.537	0.037	0.488-0.591

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.64
BASELINE TO 14 DAYS	-0.18
BASELINE TO 28 DAYS	-2.36

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 12b

CORNEAL THICKNESS CHANGE WITH GP II FOR ALL SUBJECTS

NASAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.562	0.037	0.518-0.628
AFTER 7 DAYS WEAR	0.558	0.053	0.511-0.665
AFTER 14 DAYS WEAR	0.567	0.051	0.510-0.698
AFTER 28 DAYS WEAR	0.553	0.049	0.492-0.619

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	+0.71
BASELINE TO 14 DAYS	+0.89
BASELINE TO 28 DAYS	-1.60

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant t>0.05
BASELINE TO 14 DAYS	not significant t>0.05
BASELINE TO 28 DAYS	not significant t>0.05

TABLE 12c

CORNEAL THICKNESS CHANGE WITH GP II FOR ALL SUBJECTS

NASAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.624	0.043	0.561-0.720
AFTER 7 DAYS WEAR	0.621	0.068	0.537-0.729
AFTER 14 DAYS WEAR	0.629	0.064	0.551-0.769
AFTER 28 DAYS WEAR	0.614	0.051	0.550-0.679

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-0.48
BASELINE TO 14 DAYS	-0.80
BASELINE TO 28 DAYS	-1.60

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant t>0.05
BASELINE TO 14 DAYS	not significant t>0.05
BASELINE TO 28 DAYS	not significant t>0.05

TABLE 12d

CORNEAL THICKNESS CHANGE WITH GP II FOR ALL SUBJECTS

TEMPORAL MID PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.564	0.033	0.519-0.619
AFTER 7 DAYS WEAR	0.557	0.044	0.508-0.657
AFTER 14 DAYS WEAR	0.561	0.044	0.519-0.602
AFTER 28 DAYS WEAR	0.550	0.041	0.492-0.596

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.24
BASELINE TO 14 DAYS	-0.53
BASELINE TO 28 DAYS	-2.48

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

TABLE 12e

CORNEAL THICKNESS CHANGE WITH GP II FOR ALL SUBJECTS

TEMPORAL EXTREME PERIPHERY

TIME OF MEASUREMENT	MEAN	S.D.	RANGE
BASELINE VALUE	0.611	0.039	0.534-0.678
AFTER 7 DAYS WEAR	0.600	0.056	0.525-0.710
AFTER 14 DAYS WEAR	0.609	0.045	0.544-0.677
AFTER 28 DAYS WEAR	0.592	0.050	0.522-0.664

OVERALL THICKNESS CHANGE FROM:	% CHANGE
BASELINE TO 7 DAYS	-1.80
BASELINE TO 14 DAYS	-0.33
BASELINE TO 28 DAYS	-3.12

t TEST	RESULTS
BASELINE TO 7 DAYS	not significant $t>0.05$
BASELINE TO 14 DAYS	not significant $t>0.05$
BASELINE TO 28 DAYS	not significant $t>0.05$

Table 13a

Individual Percentage Change in Central Corneal Thickness Between Baseline and 28 Days of Wear.

Central Cornea

	PATIENT	POLYCON II	GPII
Previous non-lens wearers	1. PK	- 9.17	-14.92
	2. EH	+10.99	- 4.41
	3. JT	- 1.74	+ 1.75
	4. DH	+12.15	- 1.18
	5. HL	+ .88	- 5.54
	6. KS	+ 4.06	+ 3.13
	7. GD	-10.33	-12.70
	8. JR	+ 8.48	+ 1.74
Previous soft lens wearers	9. KP	+ .20	- .78
	10. BT	- .18	- 5.10
	11. SH	- .73	+ 5.33
	12. JR	- 6.72	- 2.63
Previous hard lens wearers	13. SC	- .17	-0-
	14. DM	- 6.57	- 8.30
	15. RE	- 7.03	- 3.56
	16. TD	+ 2.59	- .58
Mean % Change		- .21	- 2.43
t-test for difference between PolyconII and GPII		not significant $t > 0.05$	

Table 13b

Individual Percentage Change in Nasal Corneal Thickness (Mid-Periphery Extreme Periphery) Between Baseline and 28 Days.

	PATIENT	MID PERIPHERAL NASAL		EXTREME PERIPHERAL NASAL	
		POLYCON II	GPII	POLYCON II	GPII
Previous non lens wearers	1. PK	-10.93	-5.32	- 7.22	- 1.93
	2. EH	+ 7.51	+3.74	+ 5.76	+ 9.35
	3. JT	- 4.03	+ .97	+ .72	- 1.07
	4. DH	+ 4.61	+ .67	- 6.15	+ .46
	5. HL	+ 1.41	-3.58	+ 4.17	+ .79
	6. KS	- 1.03	+3.91	+ 7.19	+ 2.65
	7. GD	- 8.02	-7.80	-13.53	- 9.50
	8. JR	- 3.85	- .96	- 3.88	- 5.97
Previous soft lens wearers	9. KP	+ 4.92	-7.86	+ 4.48	- 5.08
	10. BT	+ .35	+4.79	- 3.05	+ 2.00
	11. SH	+ 2.19	-10.37	- 5.55	+ 3.24
	12. JR	- 5.79	-4.51	- 2.11	- 2.37
Previous hard lens wearers	13. SL	- 3.11	- 3.40	- 3.21	- 1.45
	14. DM	-10.31	-12.04	- 7.27	- 9.12
	15. RE	- 6.49	- 3.53	- 5.64	- 9.25
	16. TD	+ 4.06	- 1.13	- 5.87	+ 2.92
	Mean % Change	- 1.78	- 2.90	- 2.57	- 1.52
	t-test for differences between PolyconII and GPII	not significant t>0.05		not significant t > 0.05	

Table 13c

Individual Percentage Change in Temporal Corneal Thickness (Mid-Periphery and Extreme Periphery) Between Baseline and 28 Days.

PATIENT	MID PERIPHERAL TEMPORAL		EXTREME PERIPHERAL TEMPORAL	
	POLYCON II	GPII	POLYCON II	GPII
previous non lens wearers				
1. PK	-12.67	+ 3.90	-12.06	-17.58
2. EH	+ 1.18	-0-	+ 8.89	+ 8.32
3. JT	- 1.78	- 3.66	+ 1.54	+ .75
4. DH	+ 4.92	+ 5.19	+11.23	+ 1.48
5. HL	+ 3.57	- 2.46	- 0.59	+ 4.57
6. KS	+ 5.55	+ 1.19	+ 9.21	+ 2.54
7. GD	-11.01	- 8.89	- 9.55	-11.45
8. JR	+ .32	- 5.96	- 6.40	- 1.23
previous hard lens wearers / previous soft lens wearers				
9. KP	- 2.07	- 4.58	- 1.52	- 5.08
10. BT	- 2.11	+ 3.64	+ .29	- 5.55
11. SH	- 4.05	- .17	- 4.15	+ 1.96
12. JR	- 5.30	- 9.12	- 6.72	- 5.41
13. SL	- 3.78	- 3.72	- .90	- 2.95
14. DM	- 7.54	- 8.15	-11.65	-12.71
15. RE	- 2.71	- 6.82	- 9.98	- 5.40
16. TD	- .95	- 1.32	- .17	+ .35
Mean % Change	- 2.40	- 2.56	- 2.03	- 2.96
t-test for differences between Polycon II and GPII	not significant $t > 0.05$		not significant $t > 0.05$	

Figure 1 Changes in corneal thickness with Polycon II for previous non-contact lens wear subjects. (Mean value for 8 eyes)

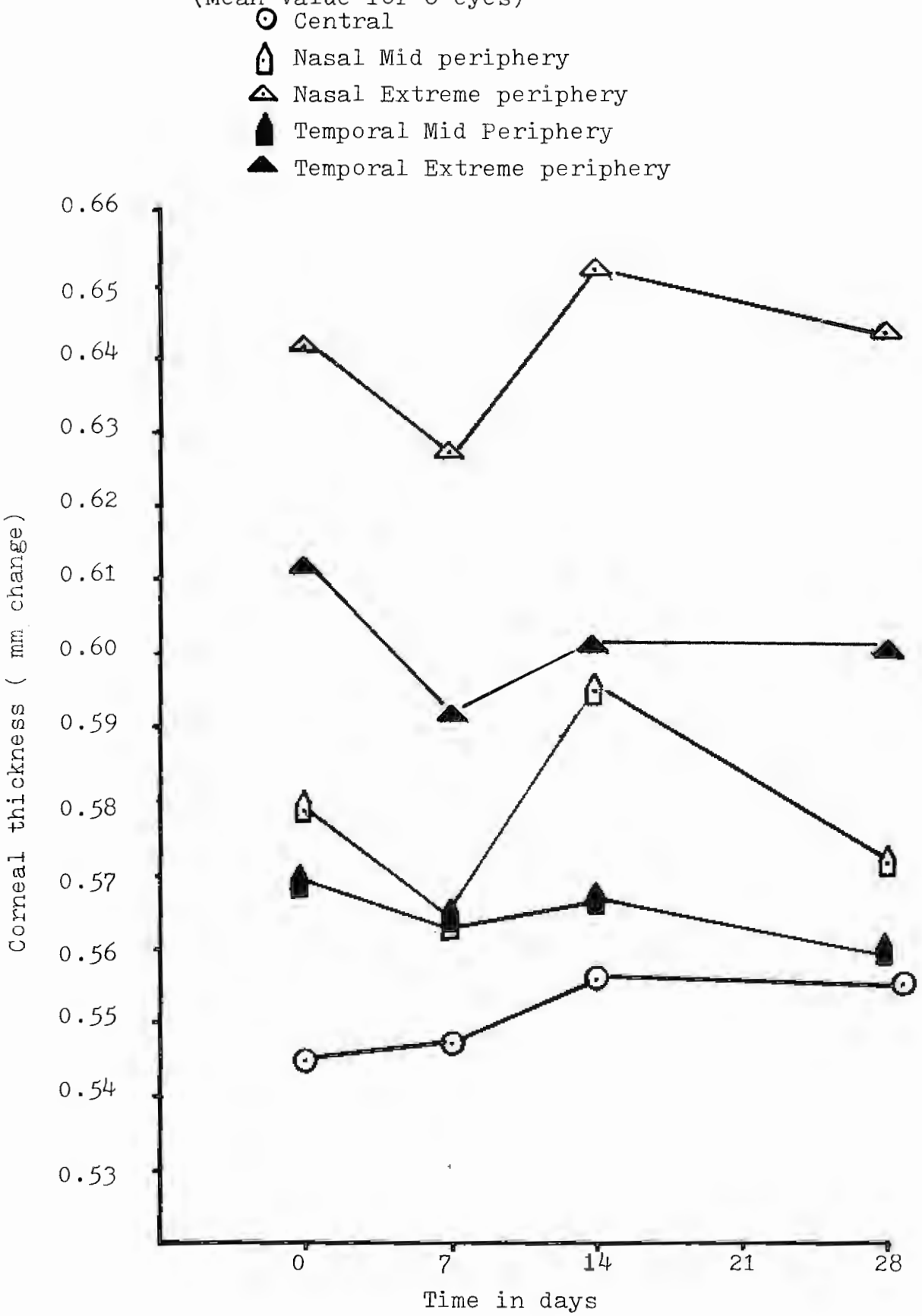


Figure 2 Changes in corneal thickness with GPII for previous non-contact lens wear subjects. (Mean value for 8 eyes)

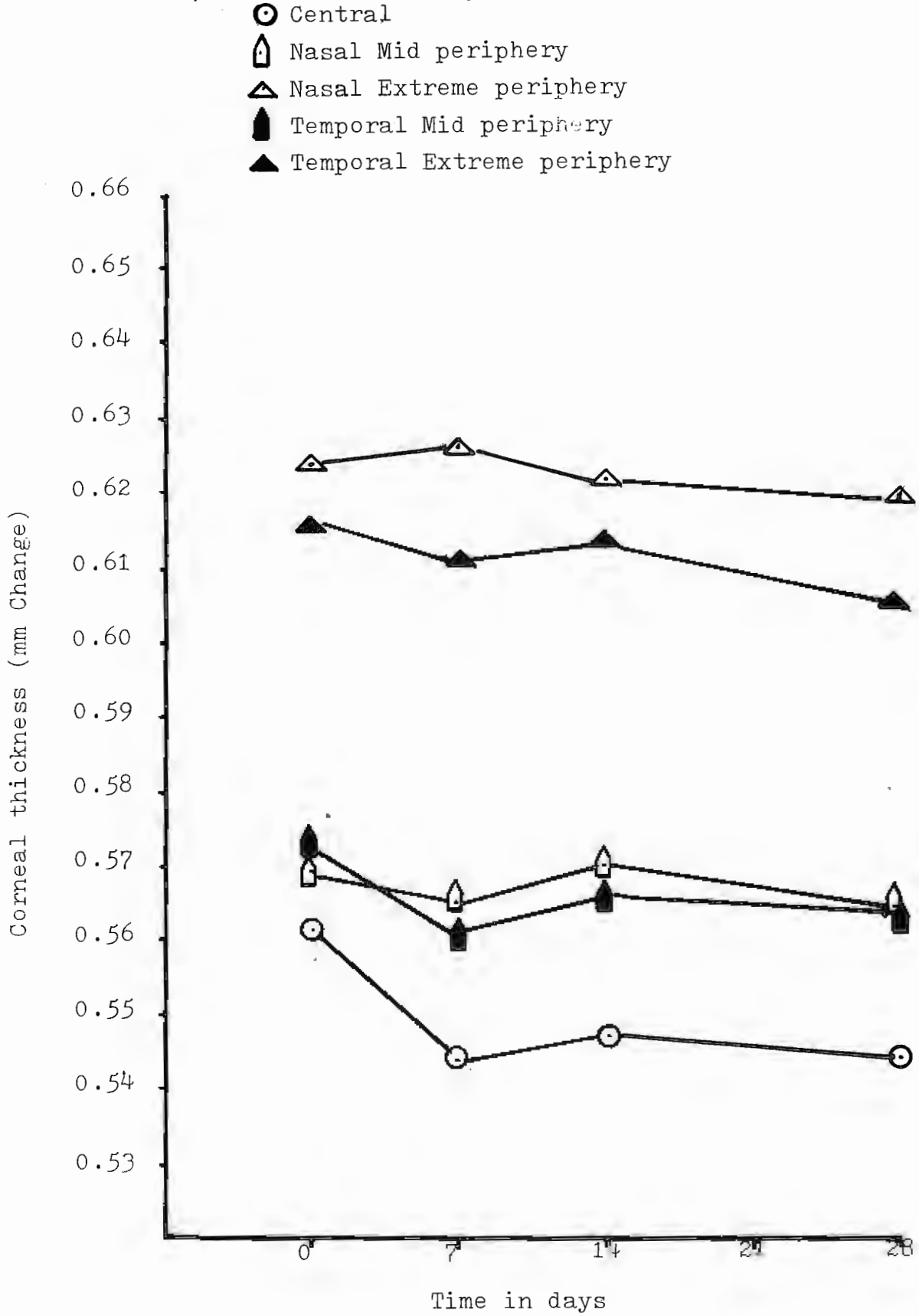


Figure 3a Percent change in corneal thickness for previous non-contact lens wear subjects. (Mean value for 8 eyes)

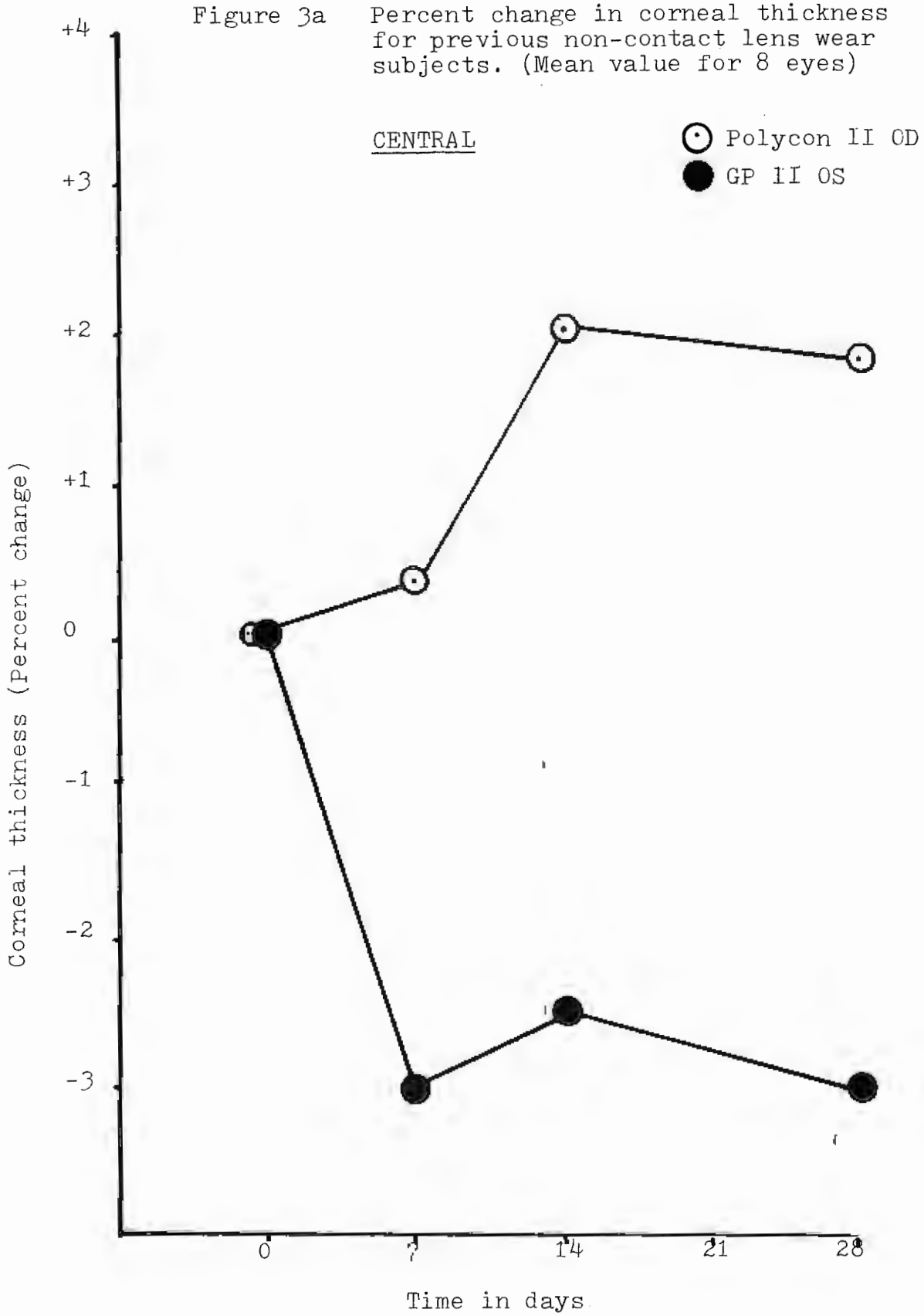


Figure 3b Percent change in corneal thickness for previous non-contact lens wear subjects. (Mean value for 8 eyes)

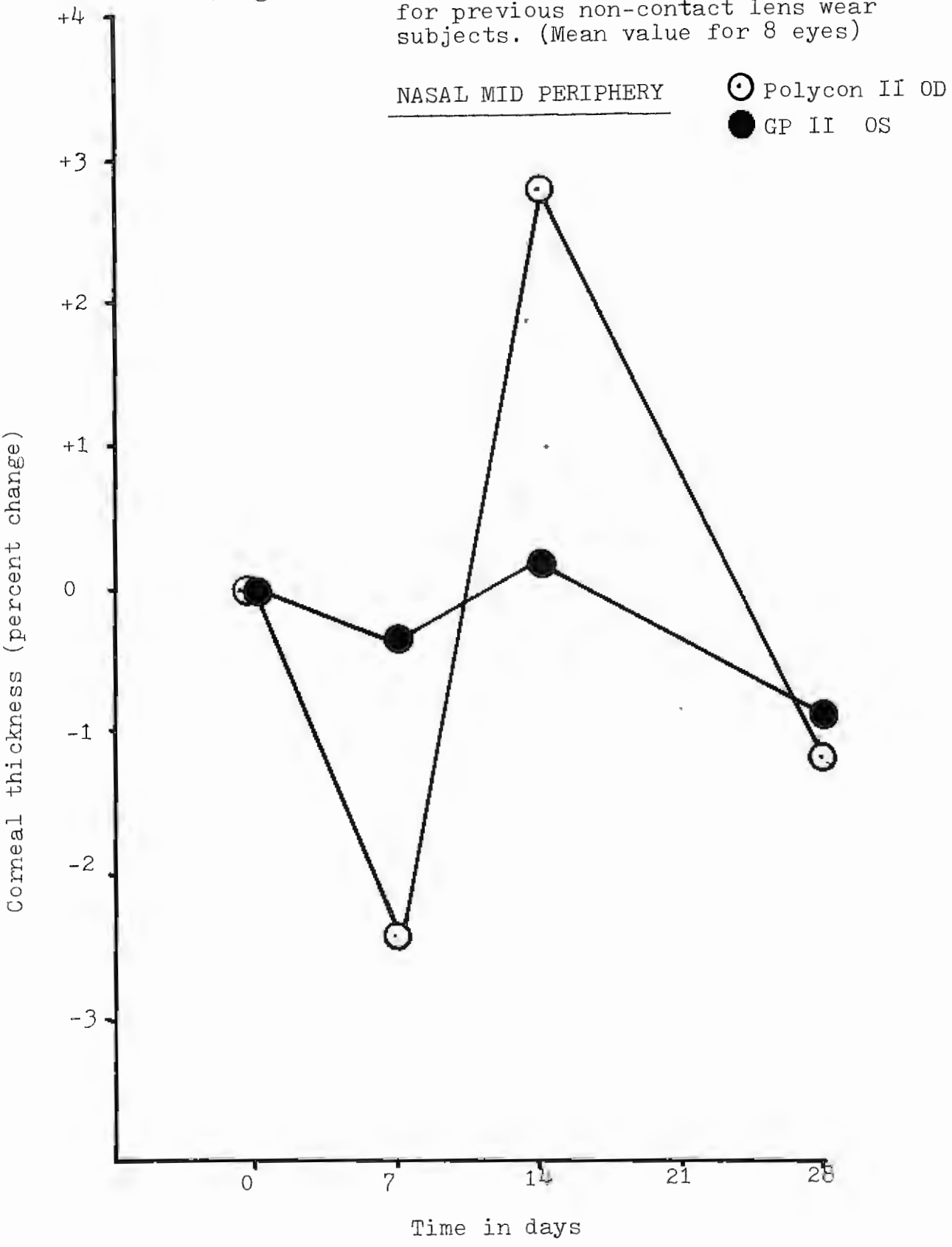


Figure 3c Percent change in corneal thickness for previous non-contact lens wear subjects. (Mean value for 8 eyes)

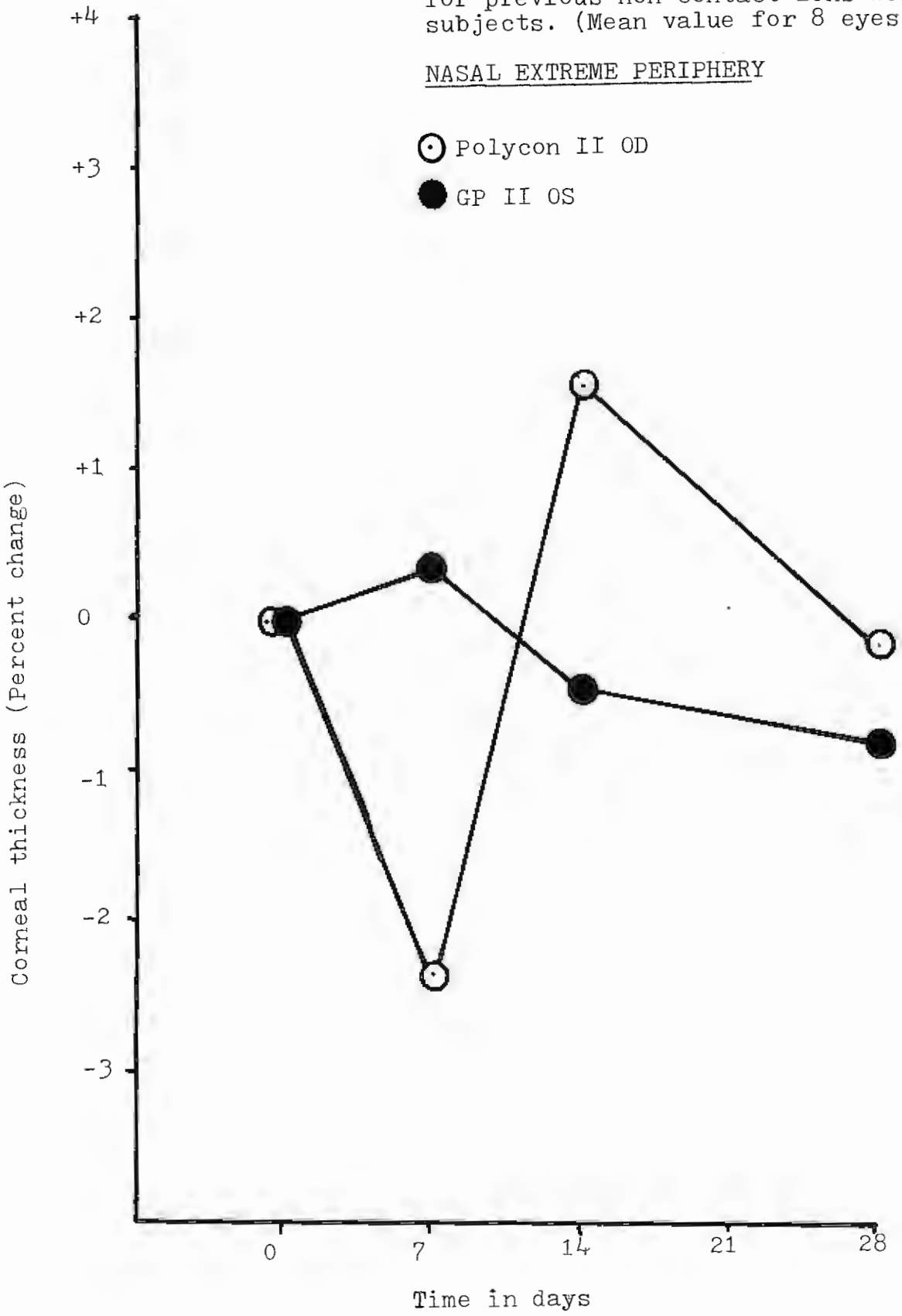


Figure 3d Percent change in corneal thickness for previous non-contact lens wear subjects. (Mean value for 8 eyes)

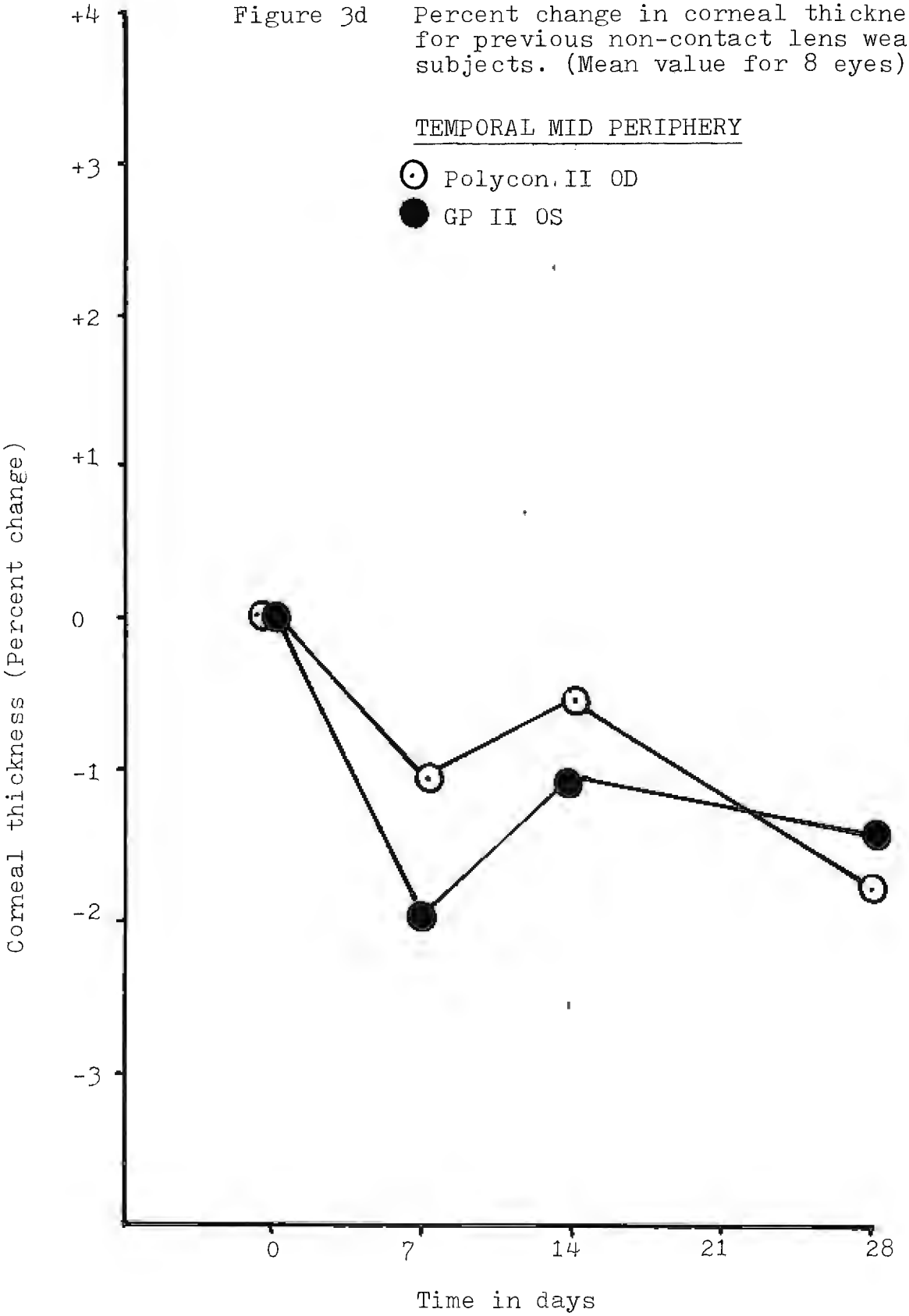


Figure 3e Percent change in corneal thickness for previous non-contact lens wear subjects. (Mean value for 8 eyes)

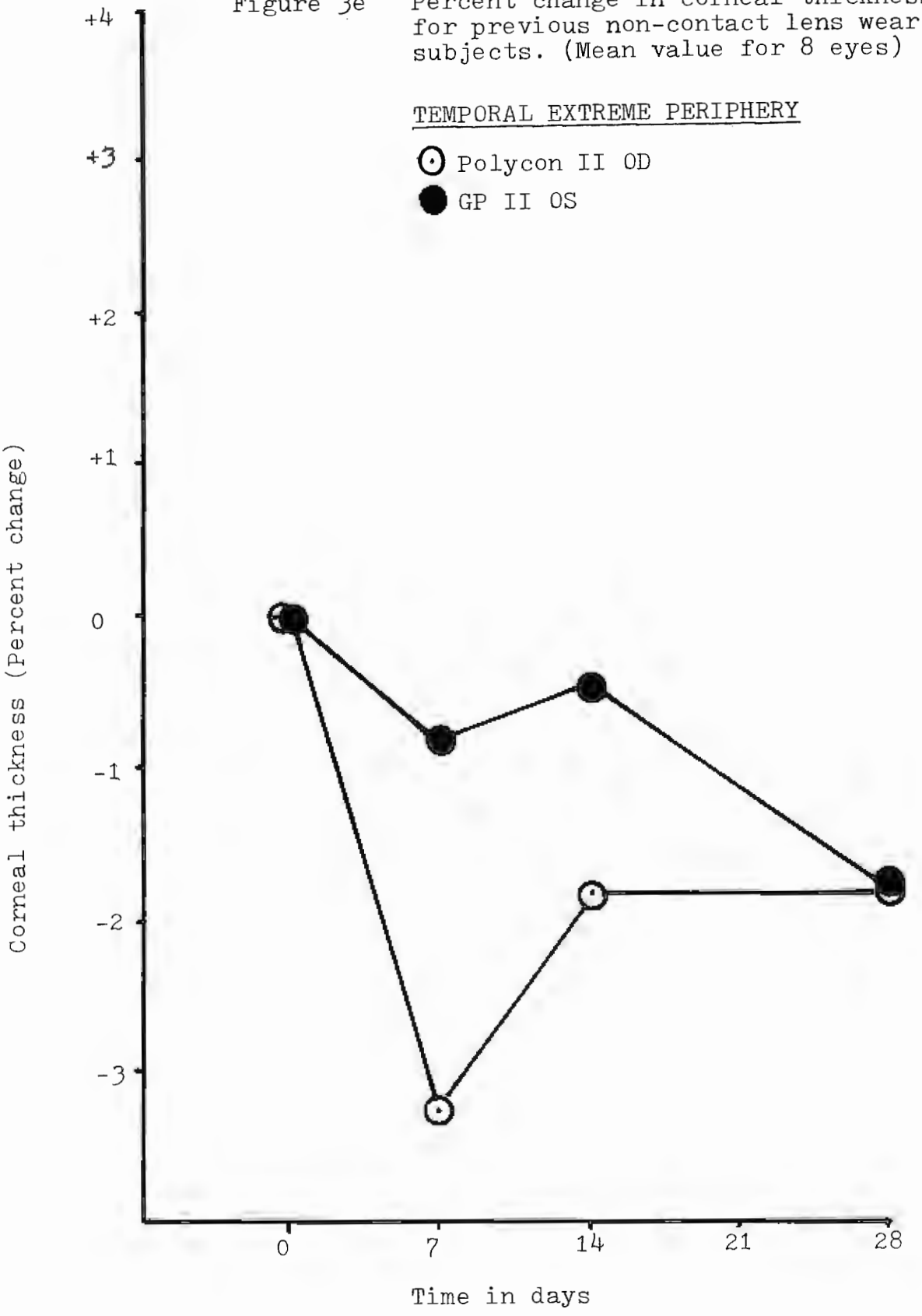


Figure 4 Changes in corneal thickness with Polycon II lens wear for previous soft contact lens wear subjects. (Mean value for 4 eyes)

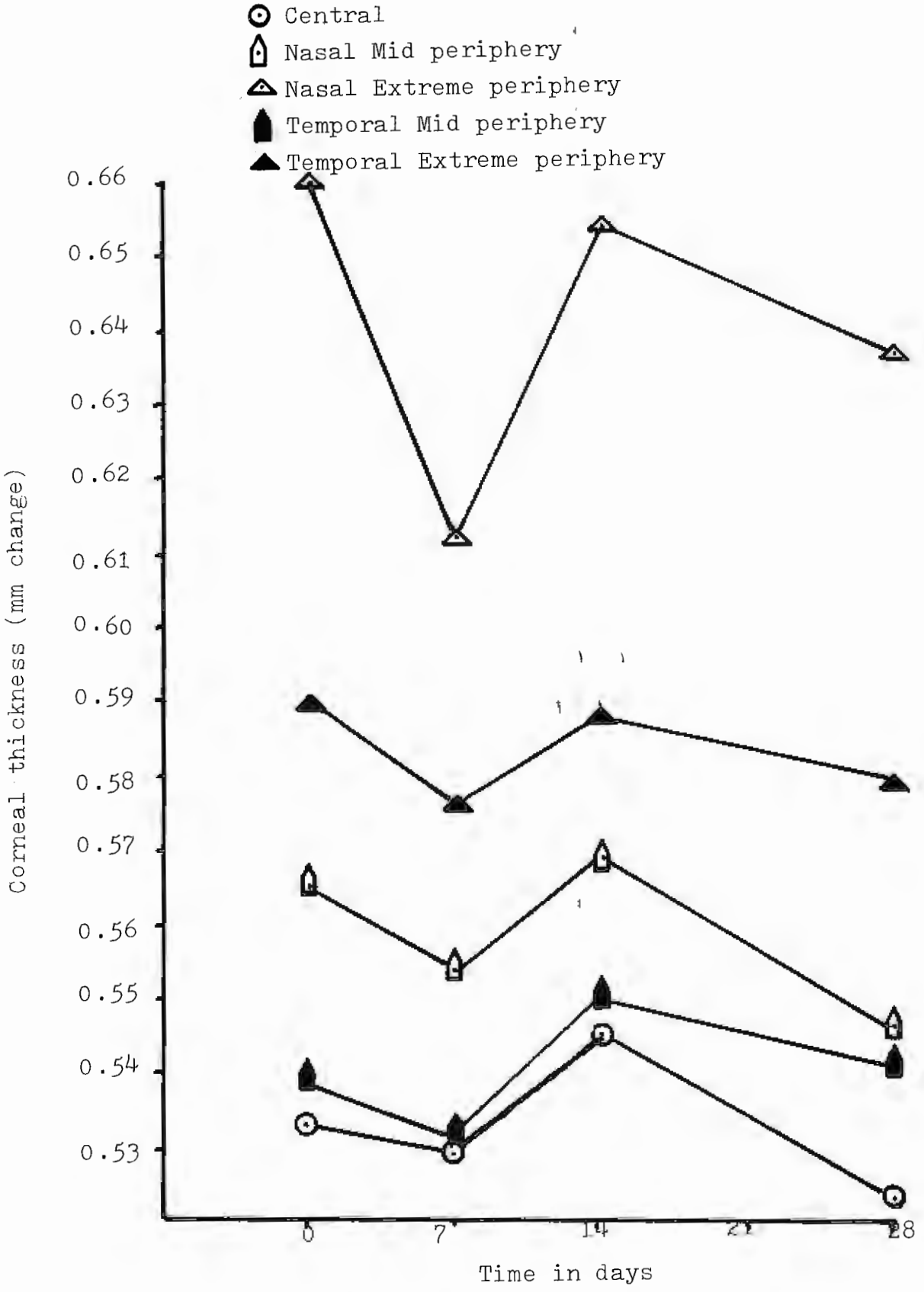


Figure 5 Changes in corneal thickness with GP II for for previous soft contact lens wear subjects. (Mean value for 4 eyes)

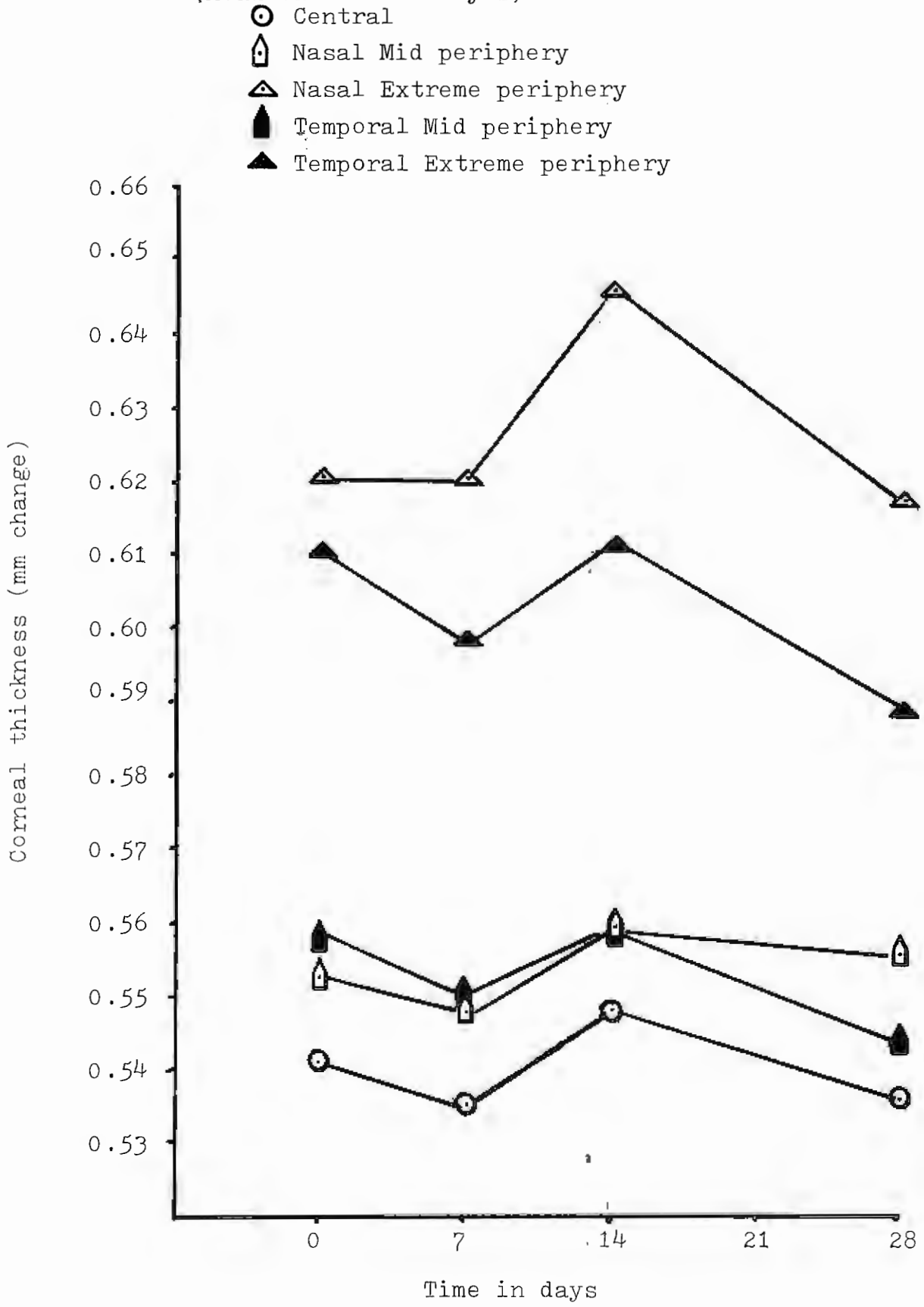


Figure 6a Percent change in corneal thickness for previous soft contact lens wear subjects. (Mean value for 4 eyes)

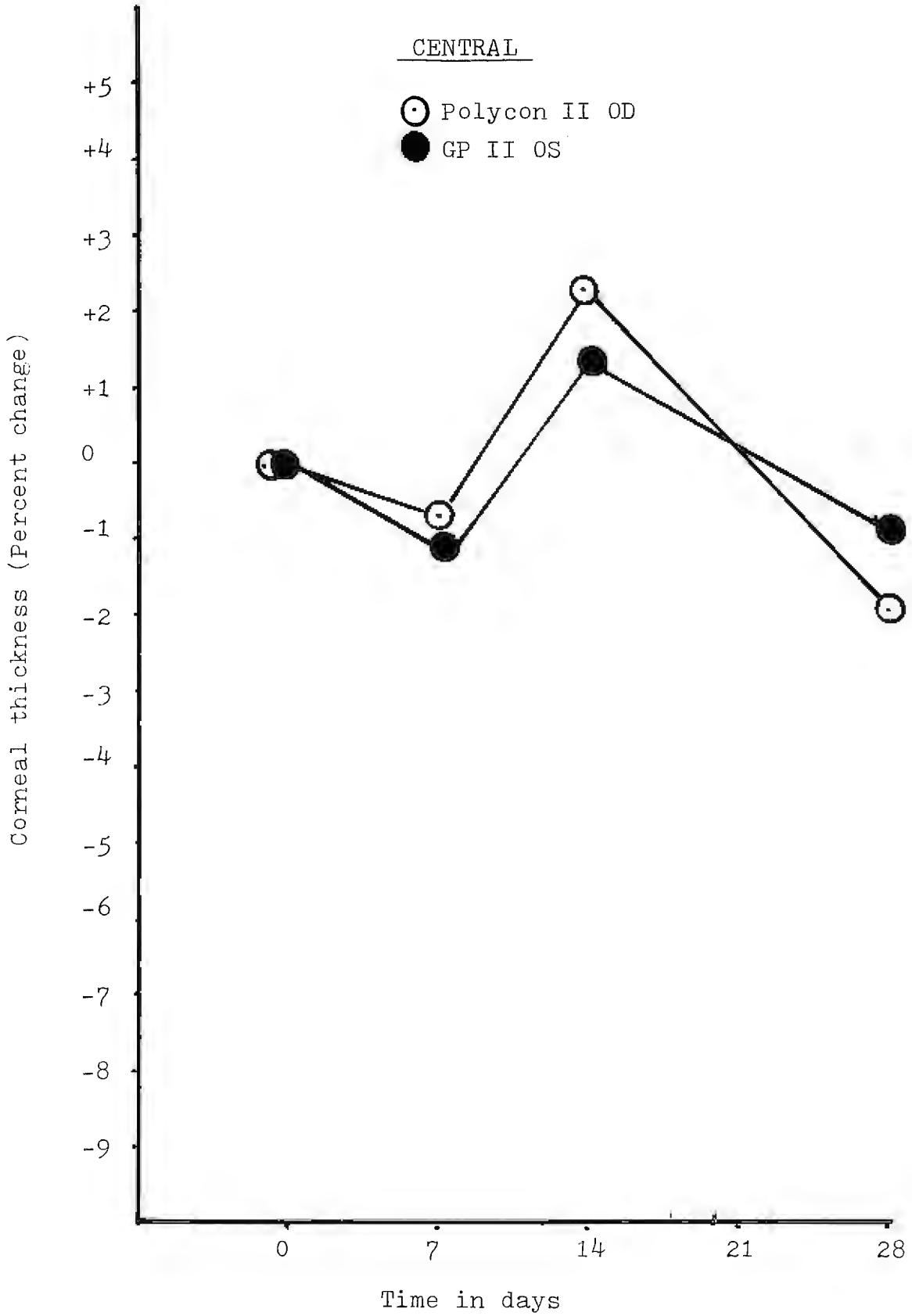


Figure 6b Percent change in corneal thickness for previous soft contact lens wear subjects. (Mean value for 4 eyes)

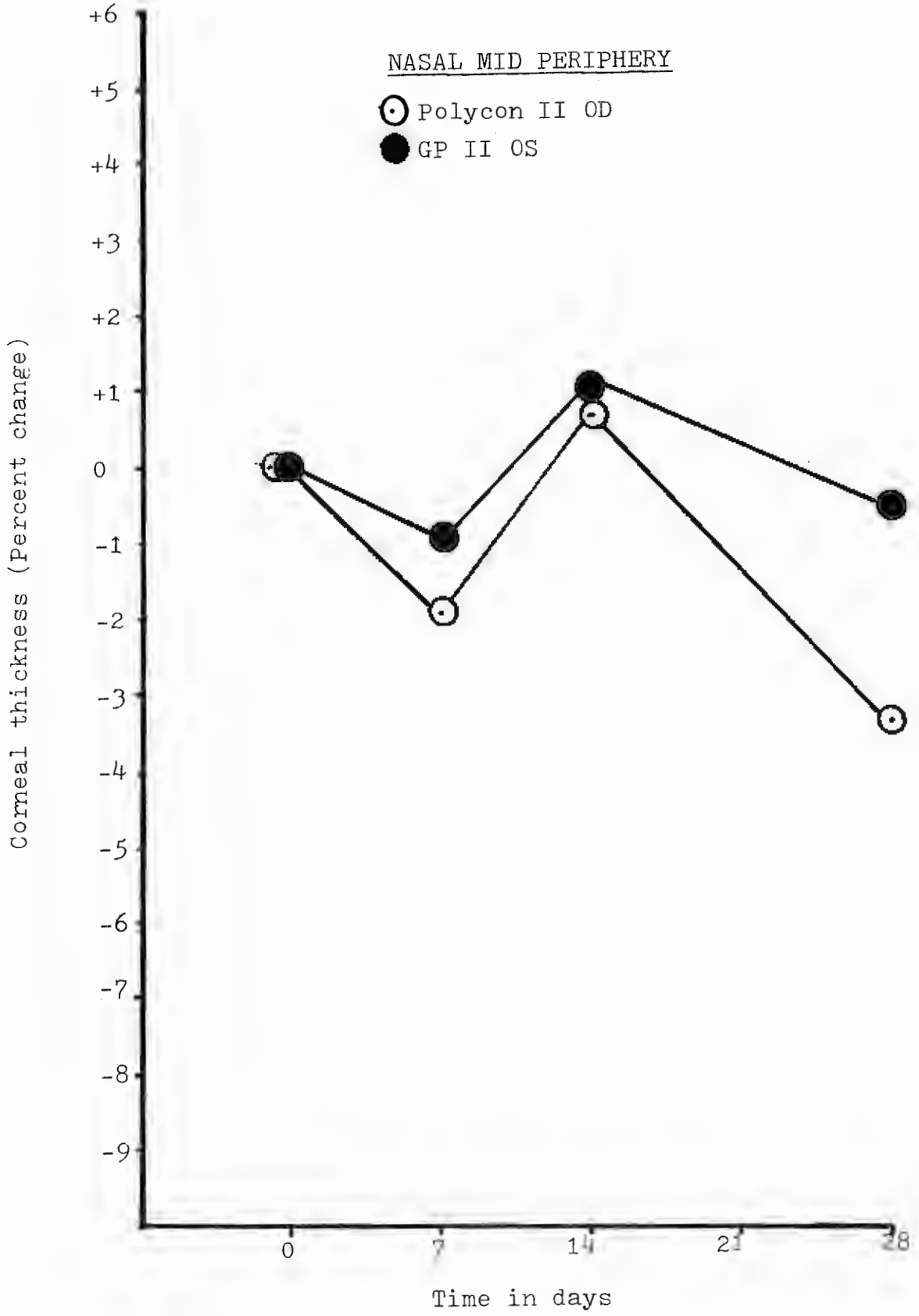


Figure 6c Percent change in corneal thickness for previous soft contact lens wear subjects. (Mean value for 4 eyes)

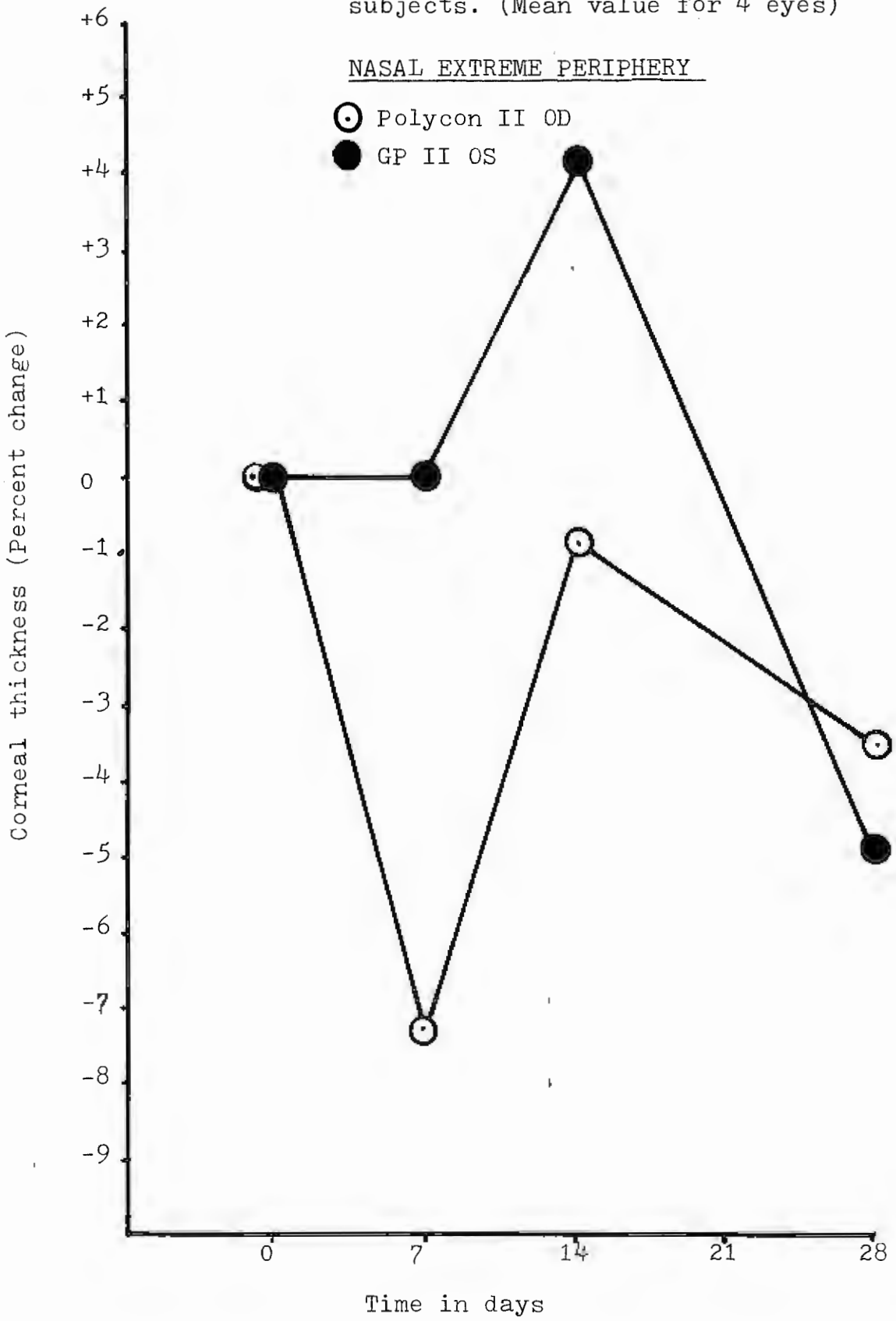


Figure 6d Percent change in corneal thickness for previous soft contact lens wear subjects. (Mean value for 4 eyes)

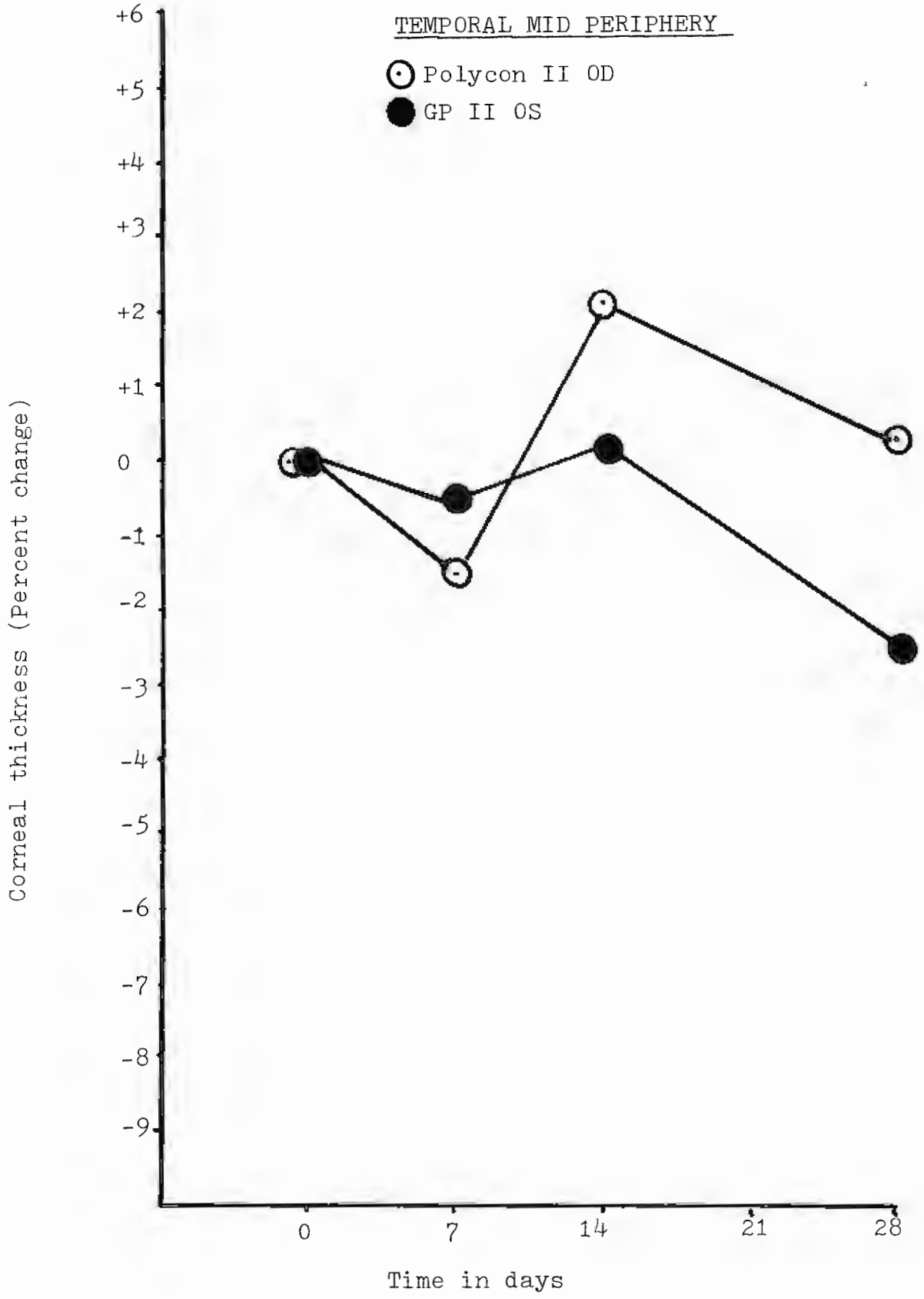


Figure 6e Percent change in corneal thickness for previous soft contact lens wear subjects. (Mean value for 4 eyes)

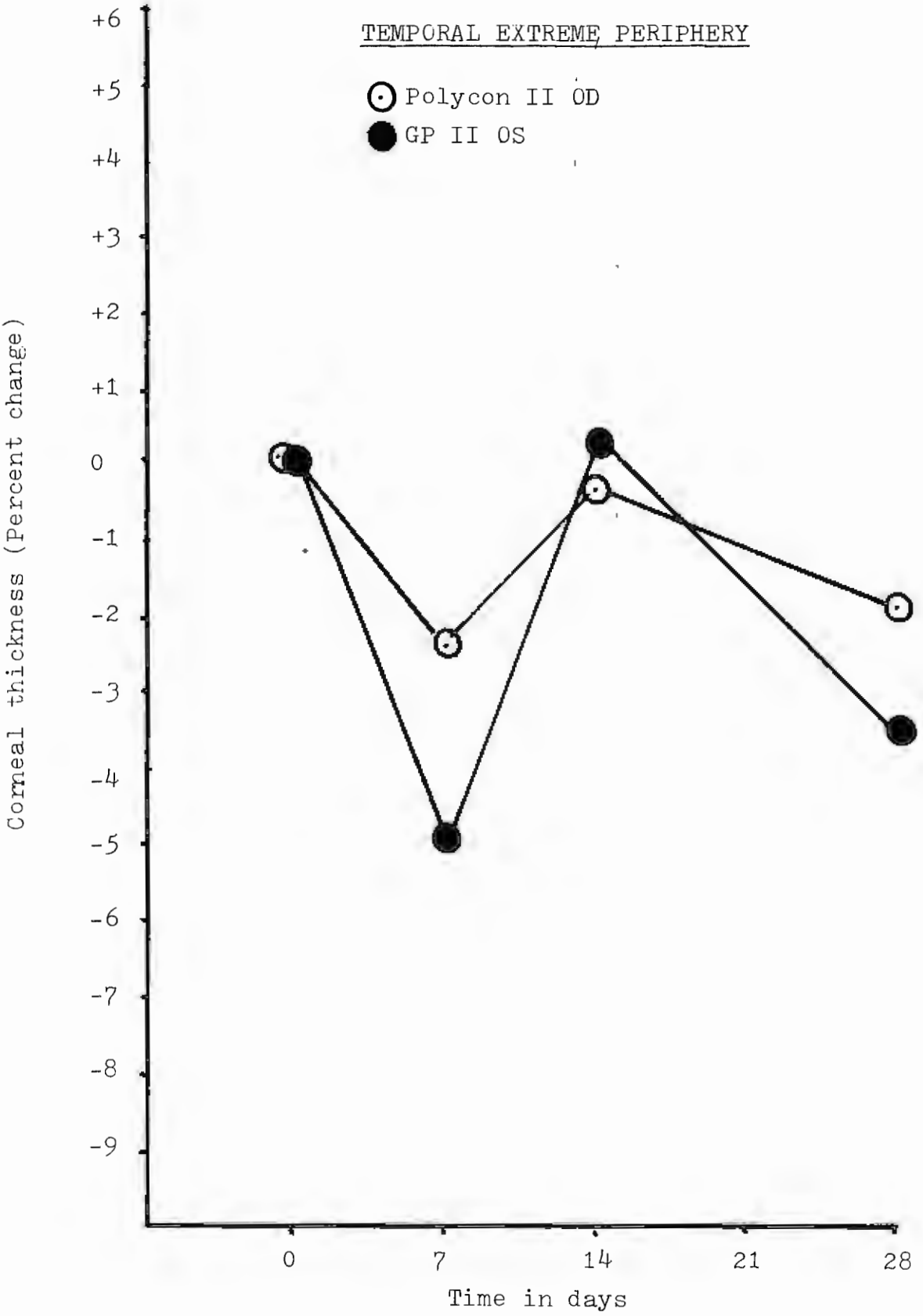


Figure 7 Changes in corneal thickness with Polycon II for previous hard contact lens wear subjects. (Mean value for 4 eyes)

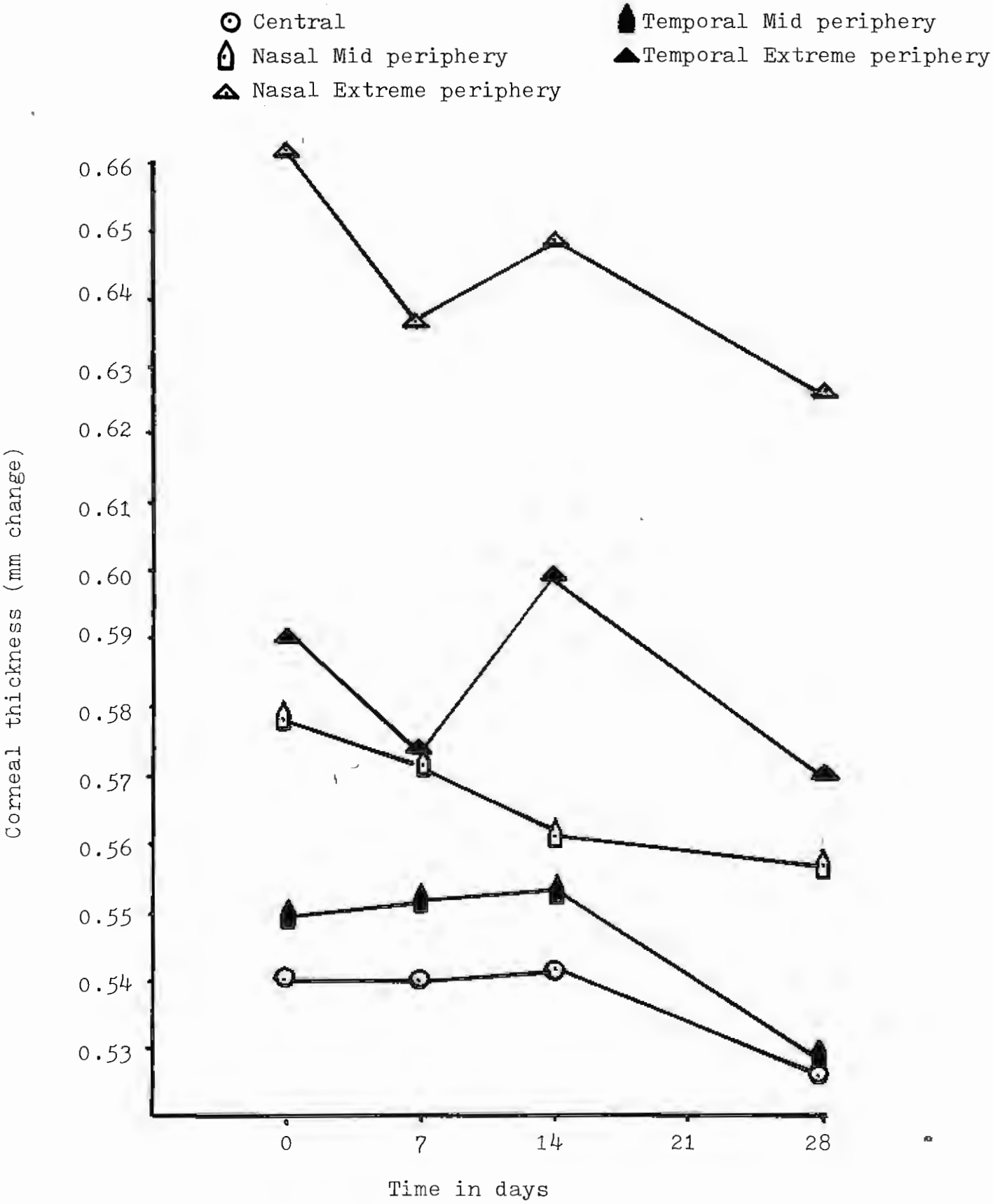
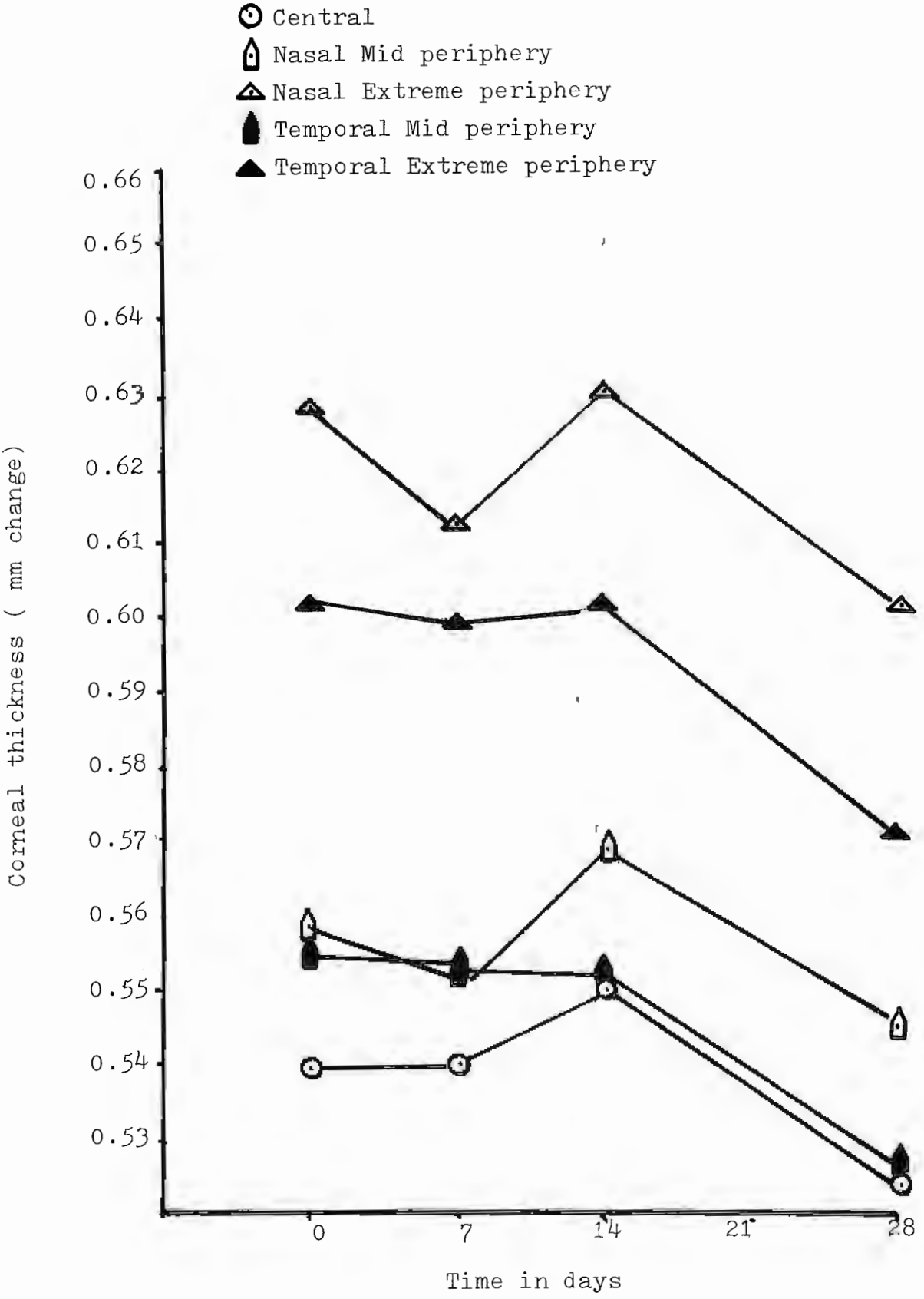


Figure 8 Changes in corneal thickness with GP II for previous hard contact lens wear subjects. (Mean value for 4 eyes)



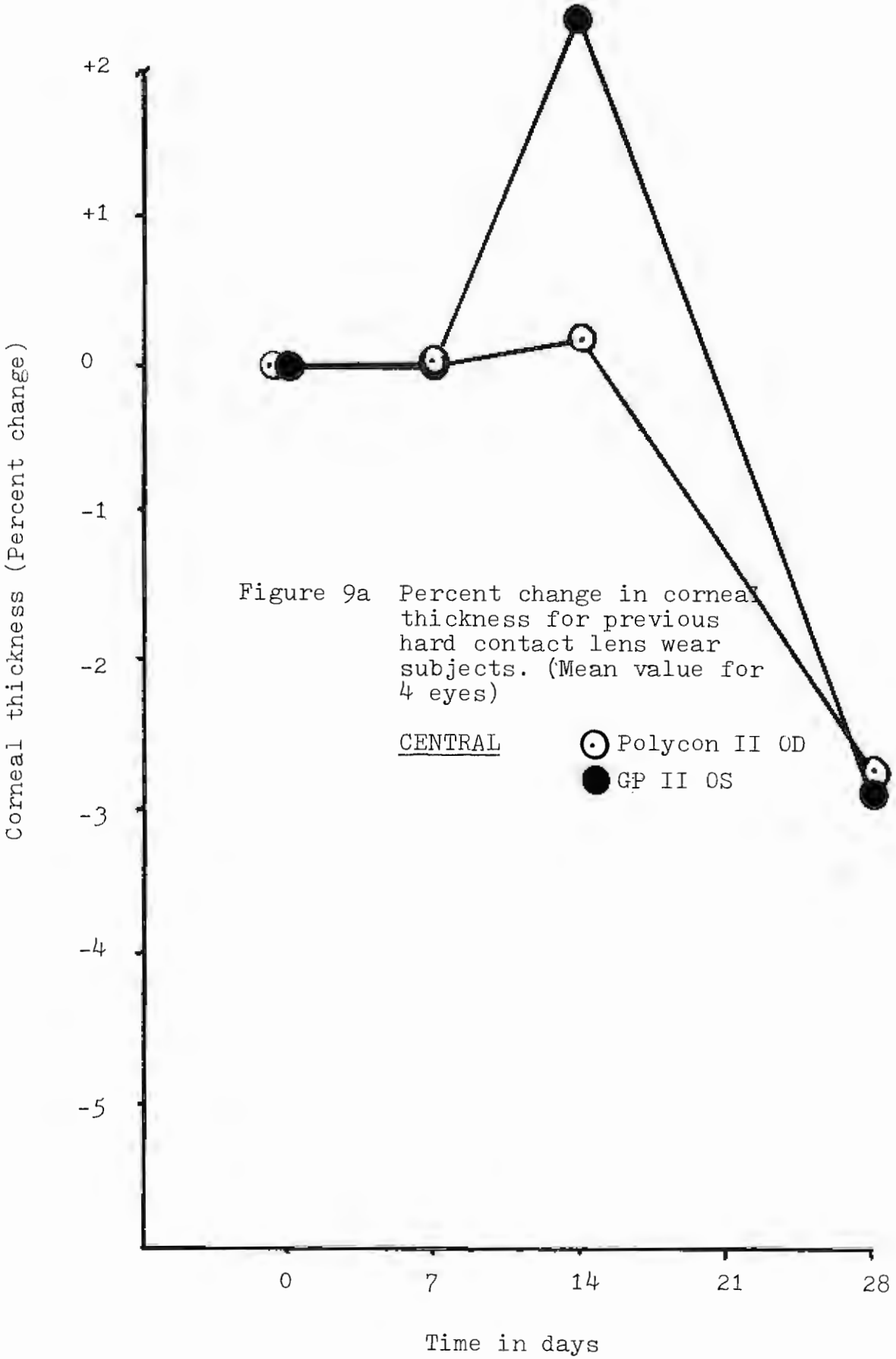


Figure 9a Percent change in corneal thickness for previous hard contact lens wear subjects. (Mean value for 4 eyes)

Figure 9b Percent change in corneal thickness for previous hard contact lens wear subjects. (Mean value for 4 eyes)

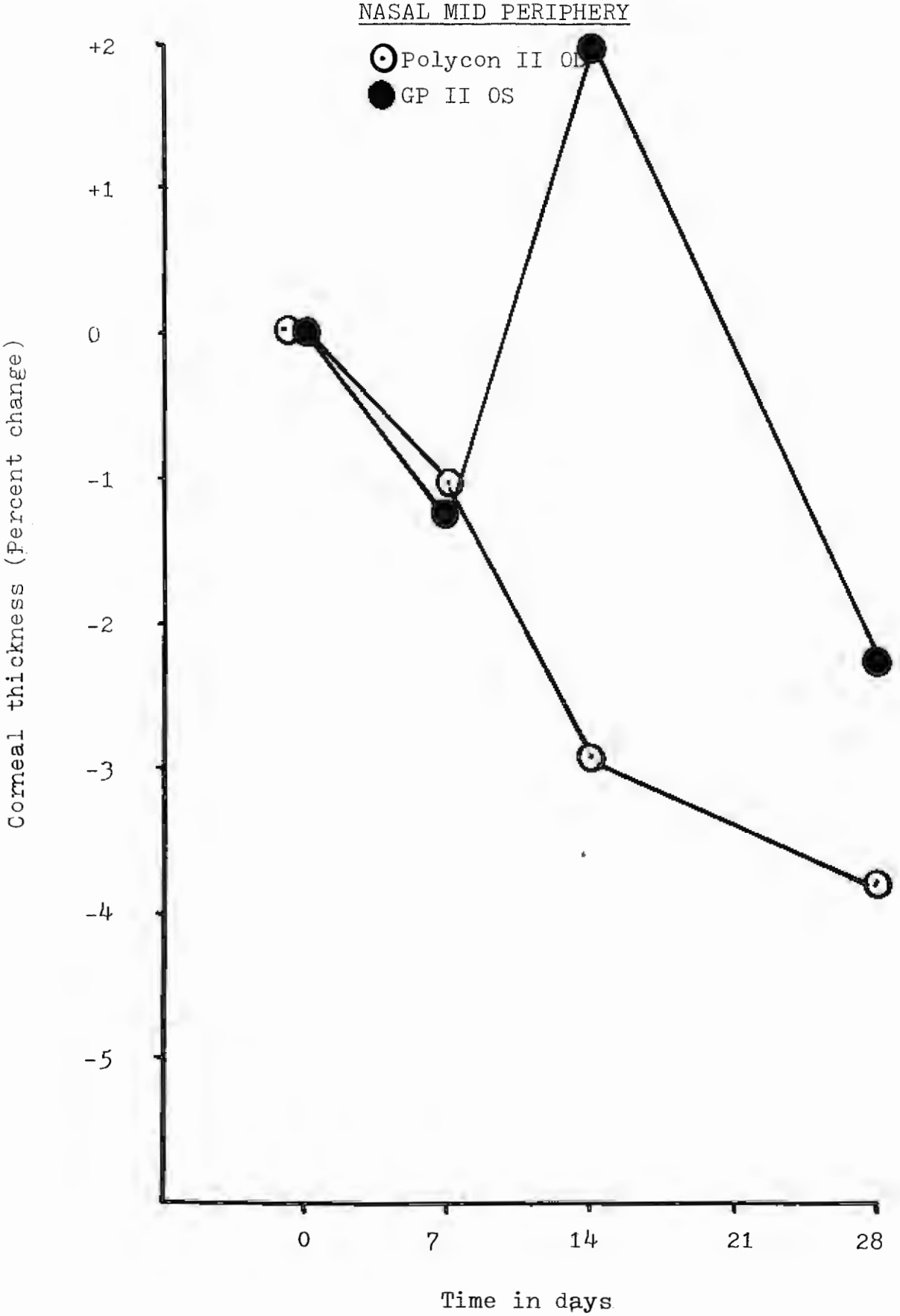


Figure 9c Percent change in corneal thickness for previous hard contact lens wear subjects. (Mean value for 4 eyes)

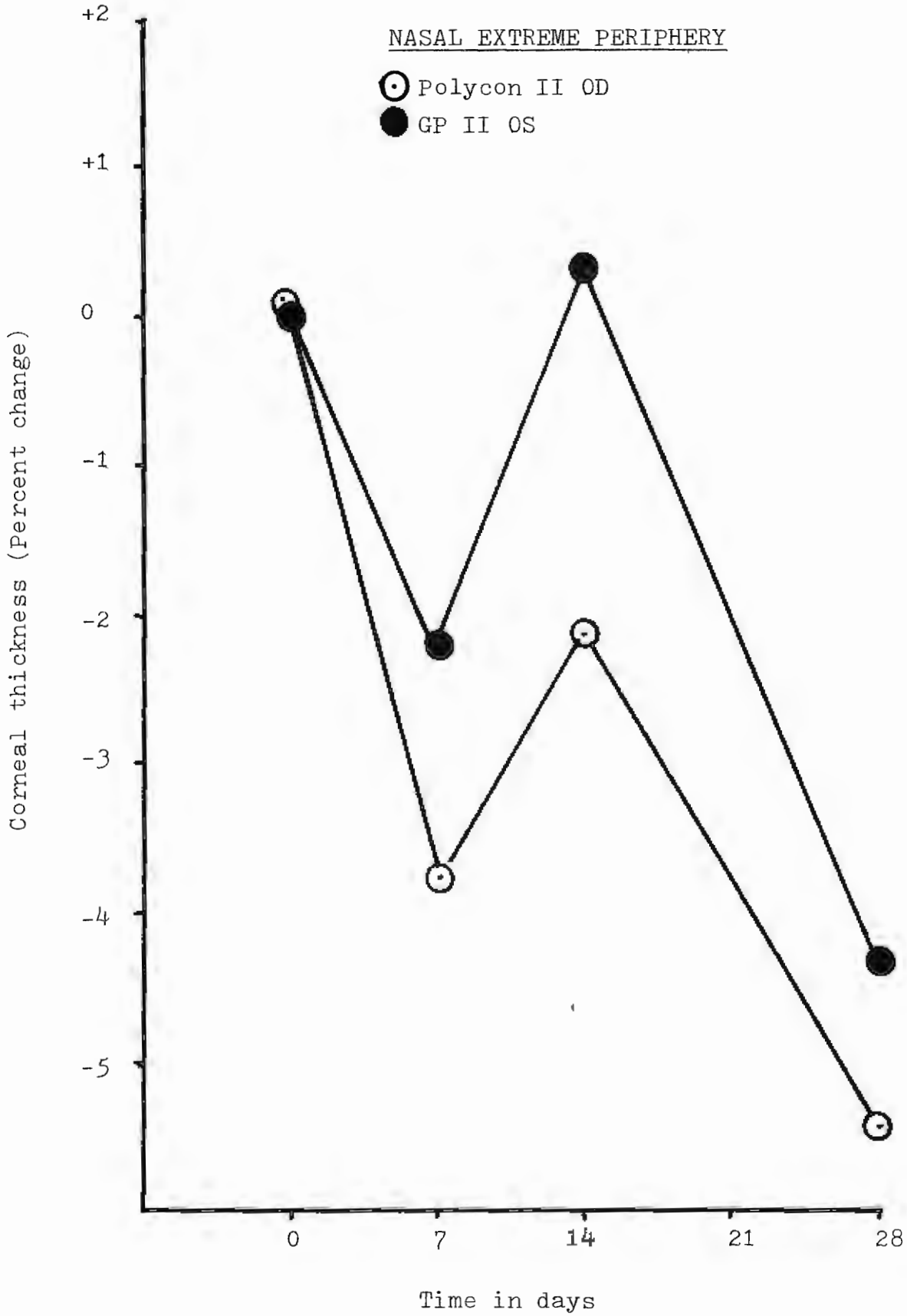


Figure 9d Percent change in corneal thickness for previous hard contact lens wear subjects. (Mean value for 4 eyes)

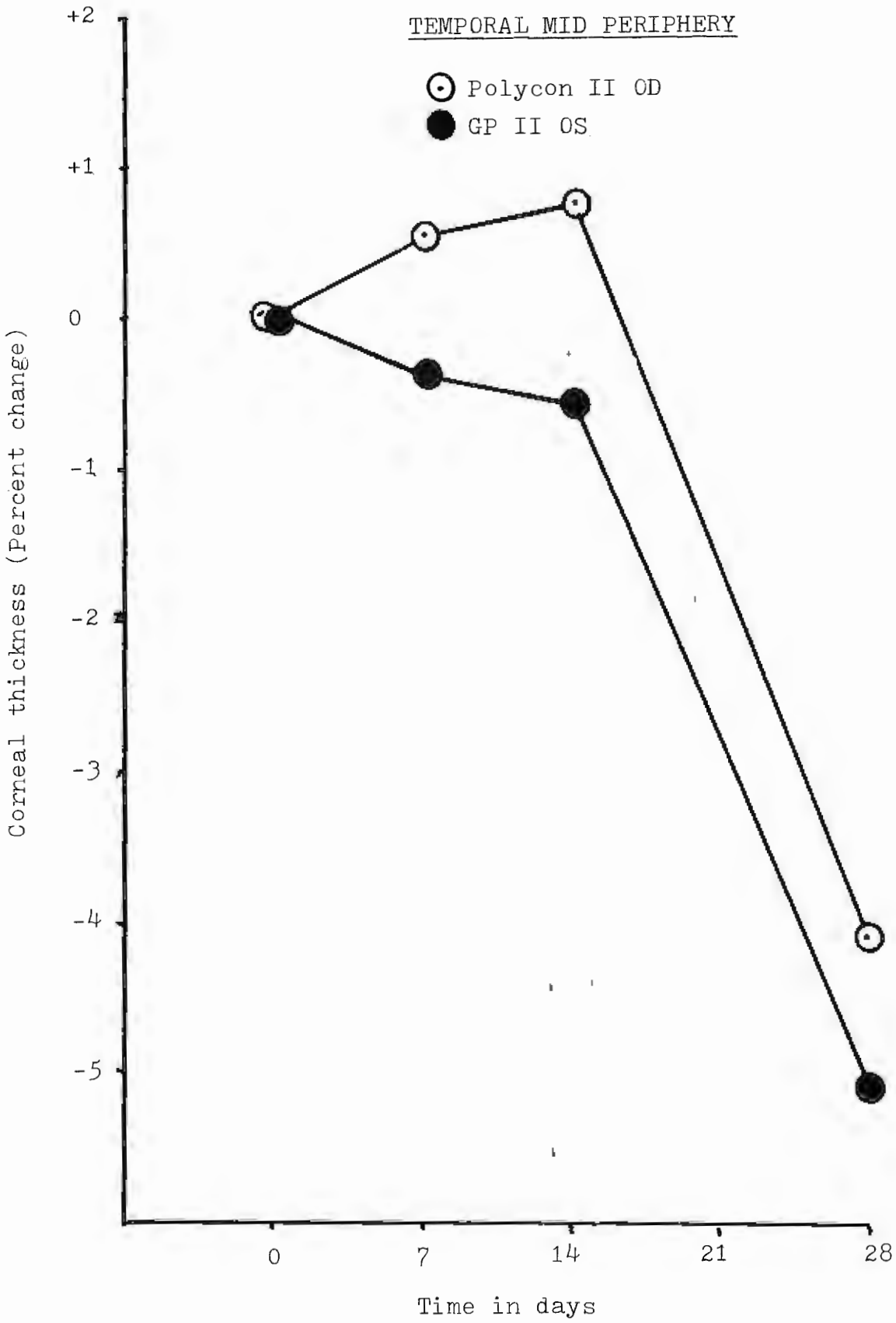


Figure 9e Percent change in corneal thickness for previous hard contact lens wear subjects. (Mean value for 4 eyes)

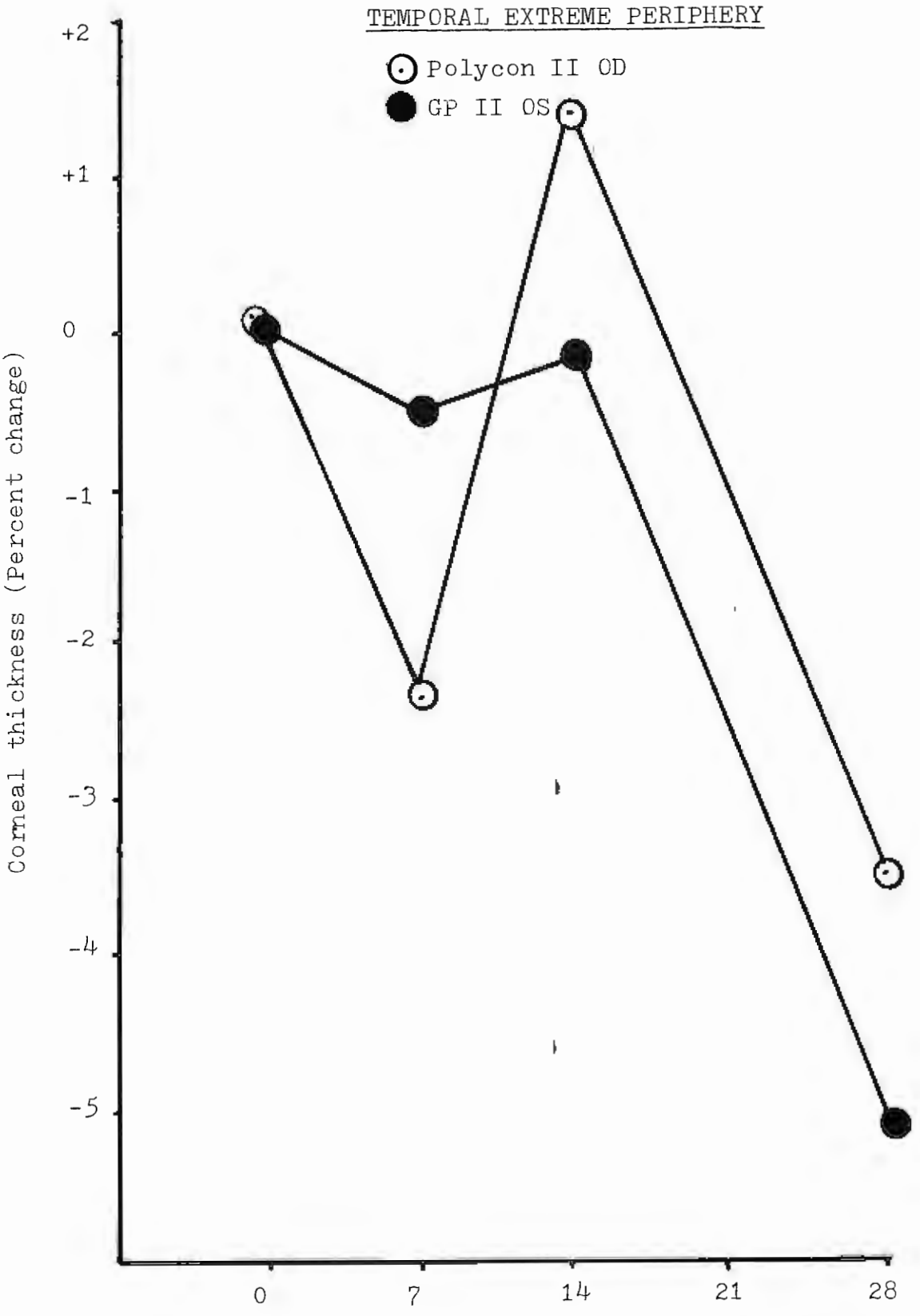


Figure 10 Changes in corneal thickness for all Polycon II lens wear subjects. (Mean Value for 16 eyes)

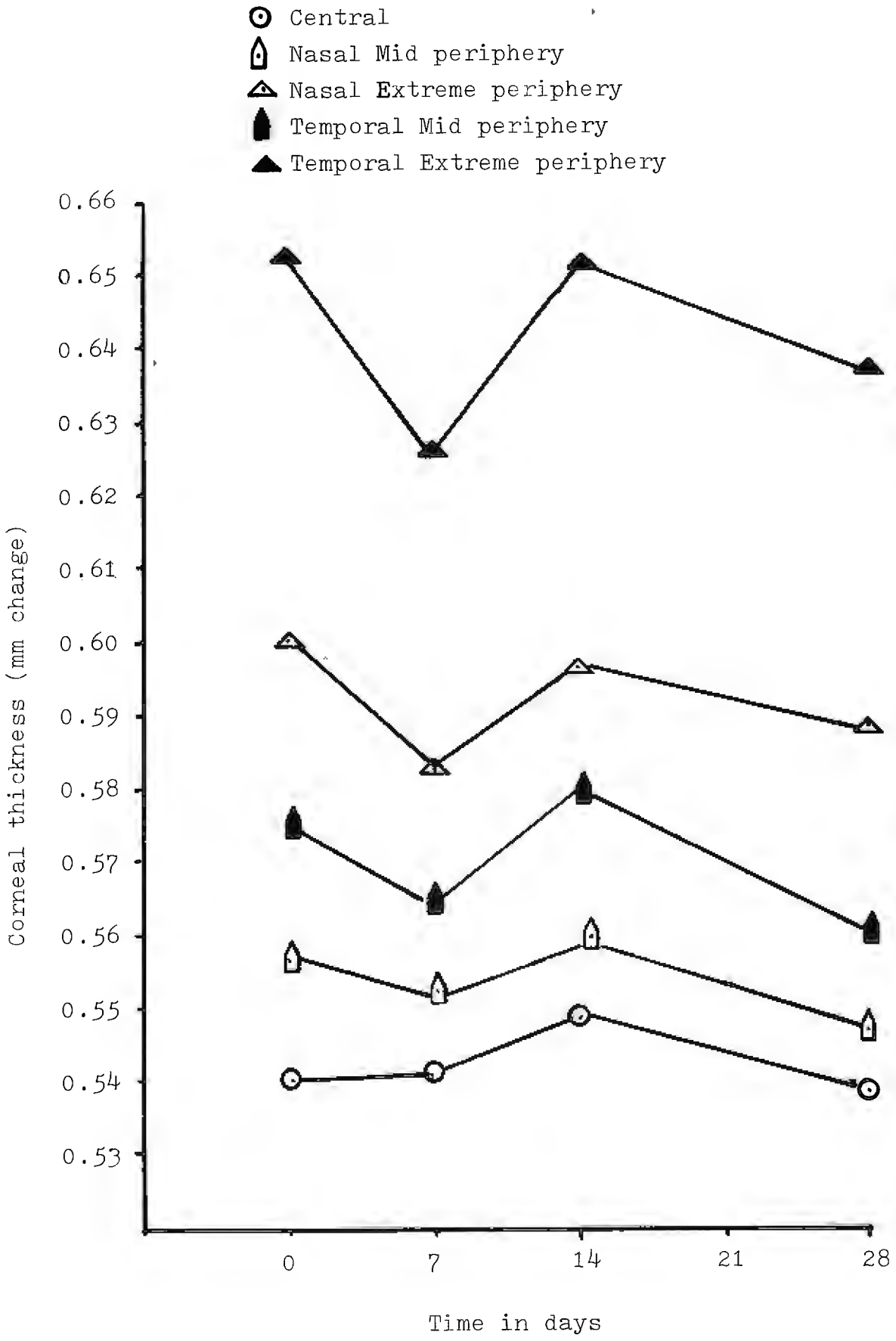


Figure 11 Changes in corneal thickness for all GP II Lens wear subjects. (Mean value for 16 eyes)

- Central
- Nasal Mid periphery
- Nasal Extreme periphery
- Temporal Mid periphery
- Temporal Extreme periphery

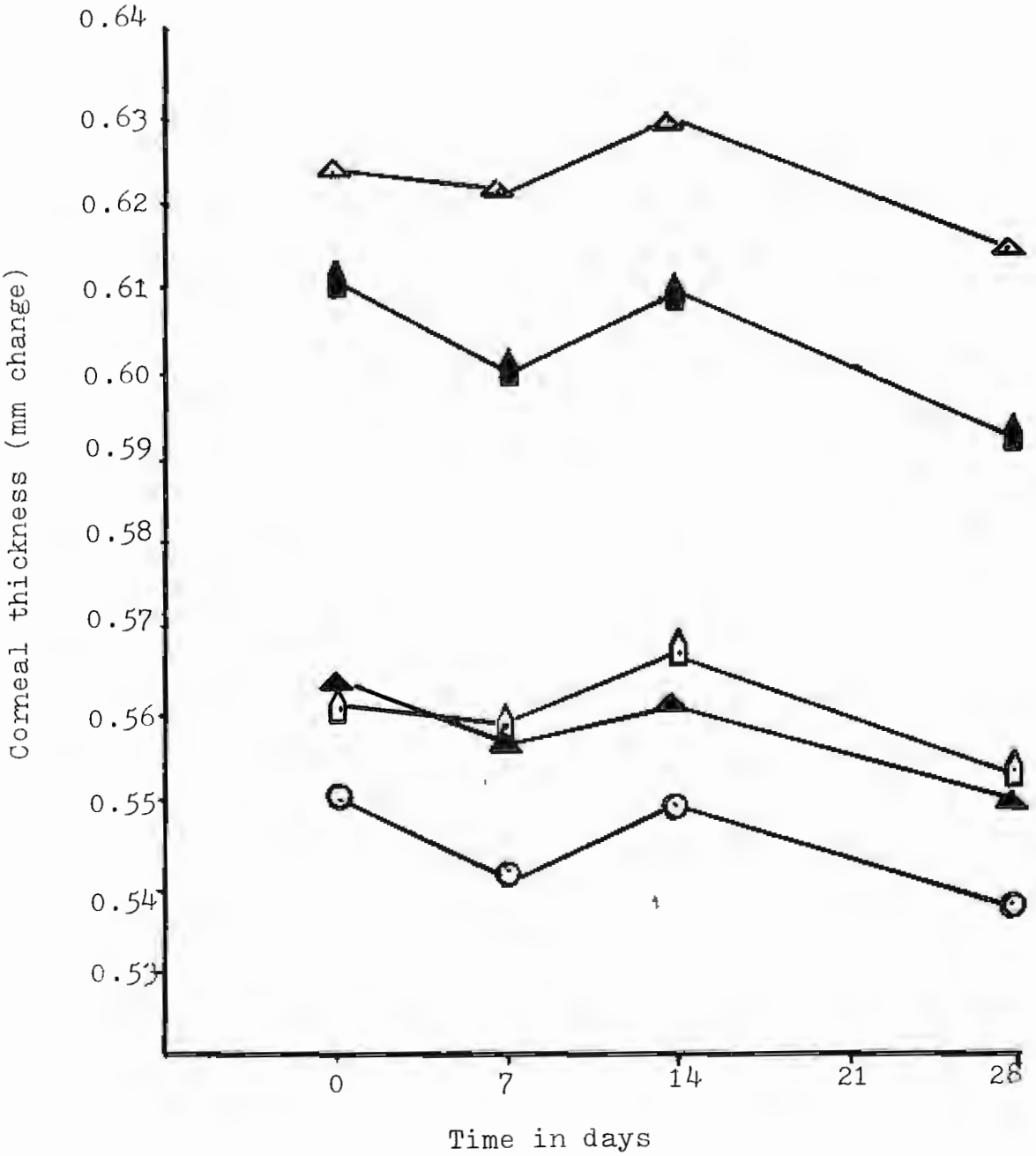


Figure 12a Percent change in corneal thickness for all subjects. (Mean value for 16 eyes)

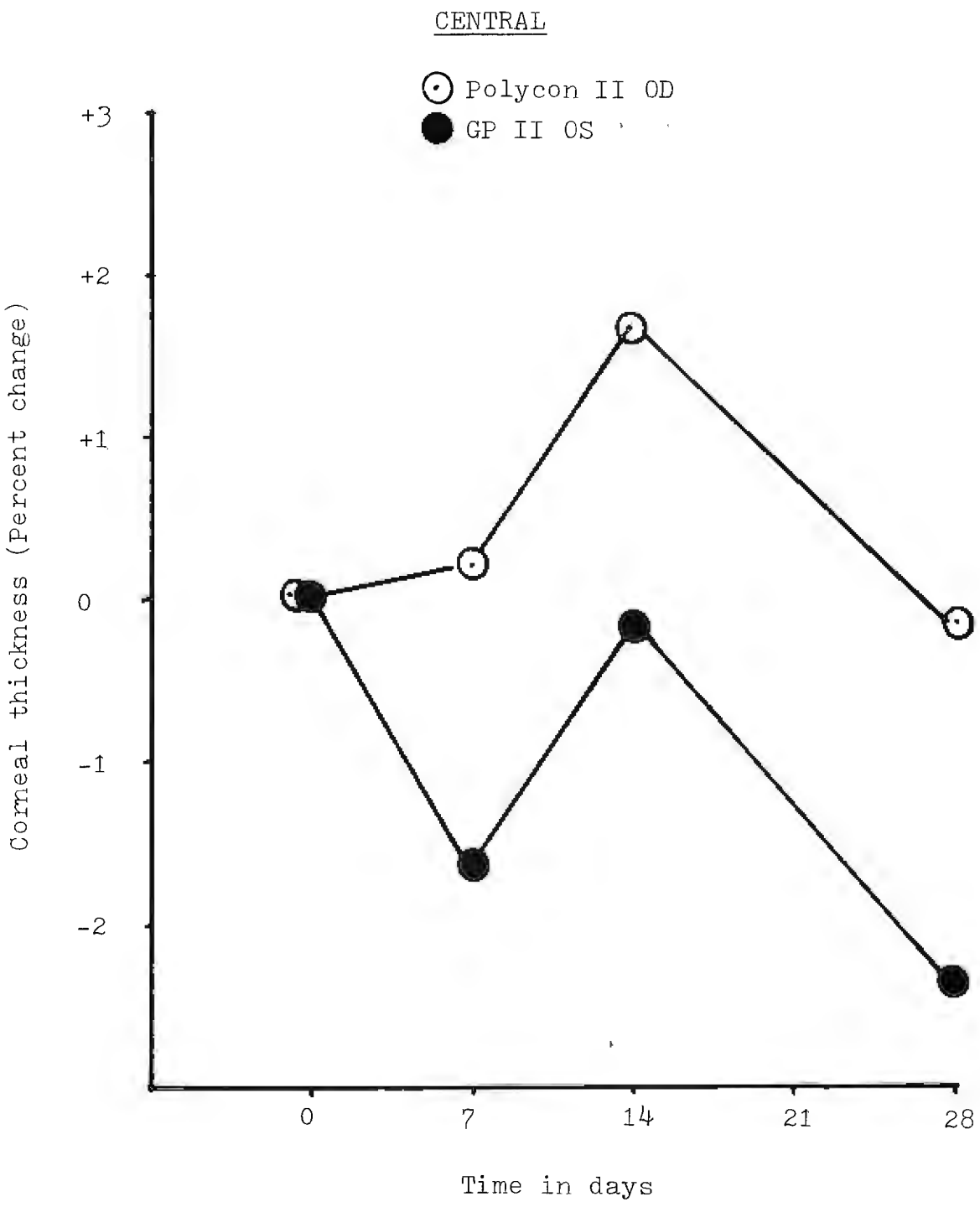


Figure 12b Percent change in corneal thickness for all subjects. (Mean value for 16 eyes)

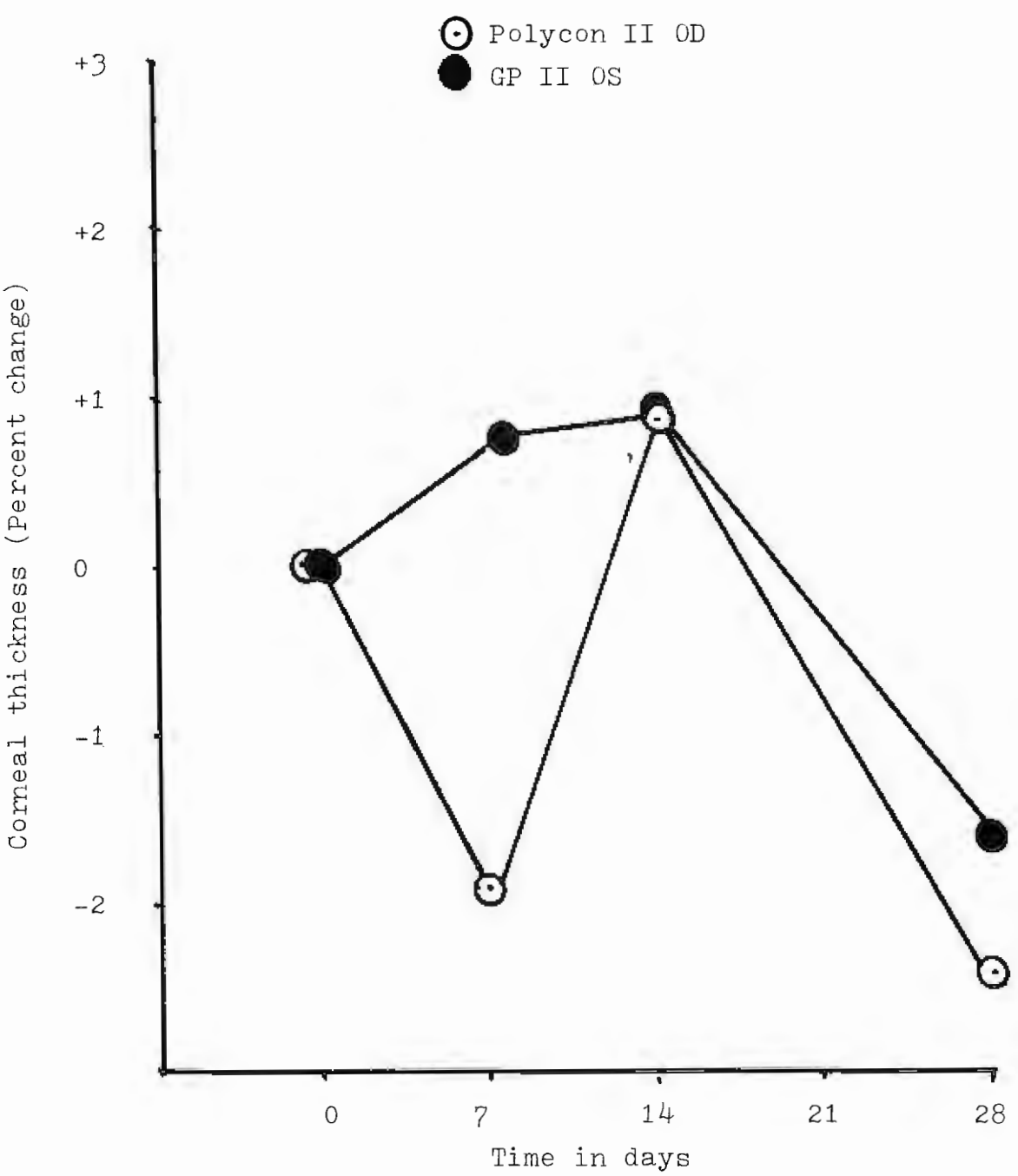


Figure 12c Percent change in corneal thickness for all subjects. (Mean value for 16 eyes)

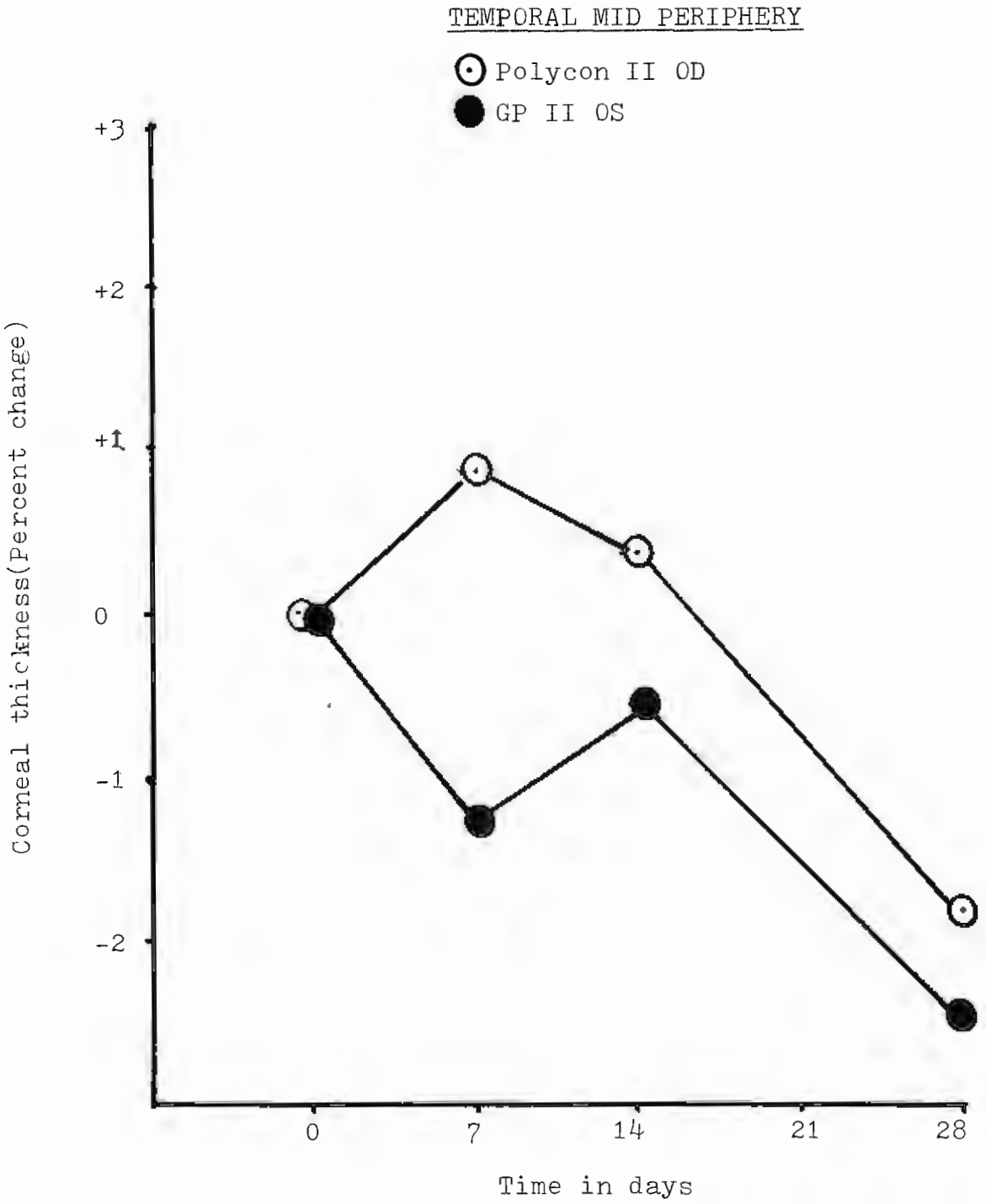


Figure 12d Percent change in corneal thickness for all subjects. (Mean value for 16 eyes)

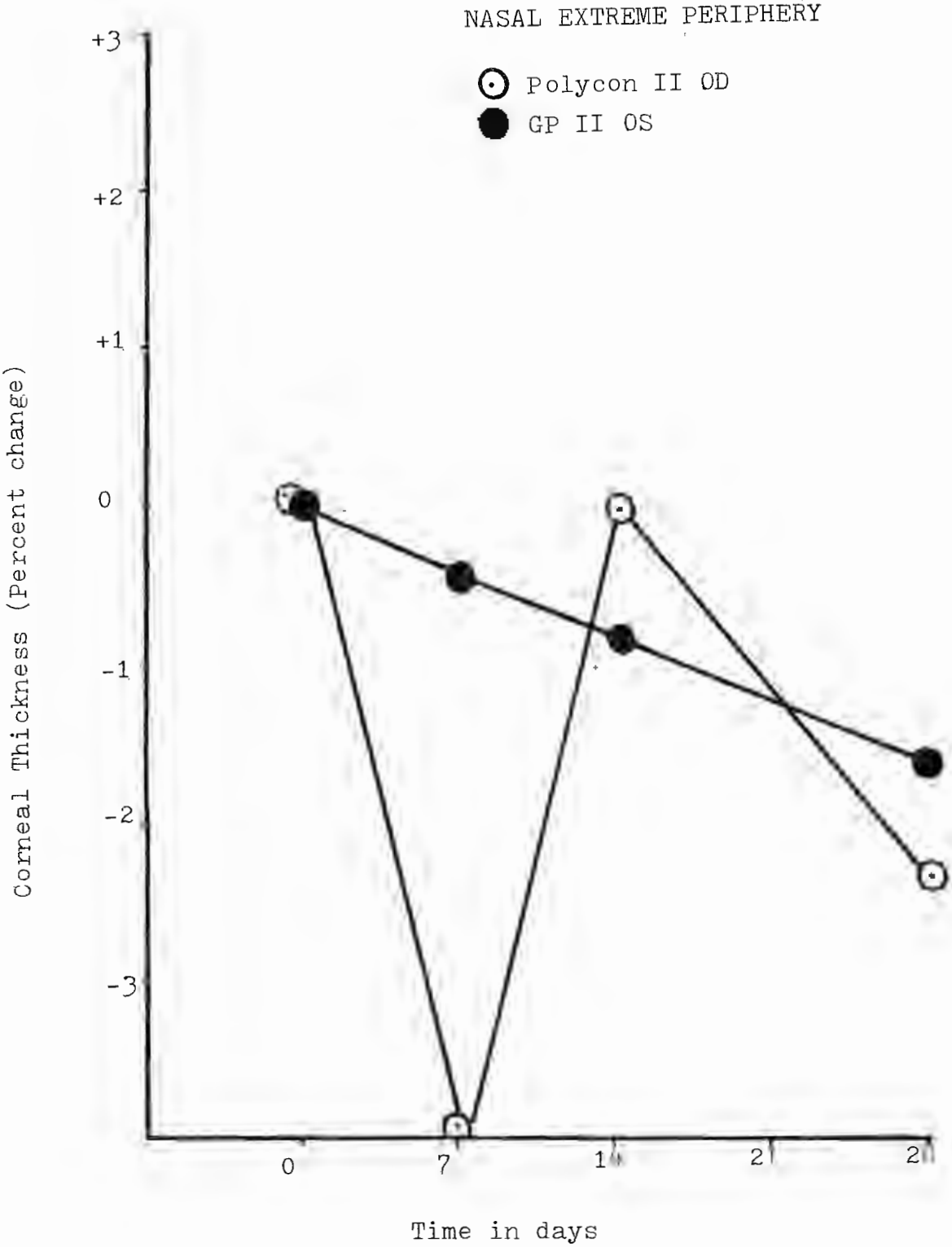


Figure 12e Percent change in corneal thickness for all subjects. (Mean value for 16 eyes)

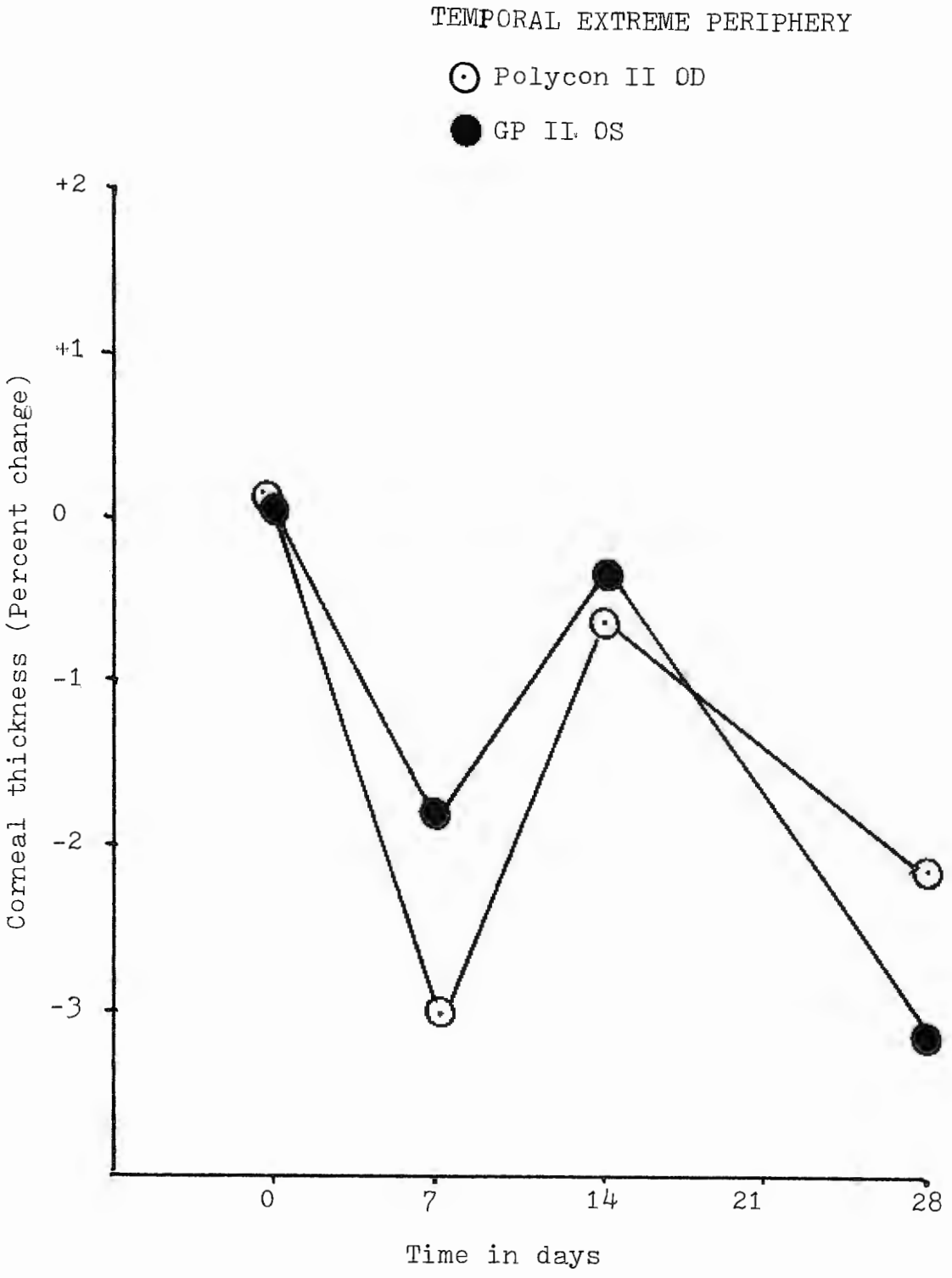


Figure 13 Individual percent change for central cornea thickness between baseline and 28 days of Polycon II wear.

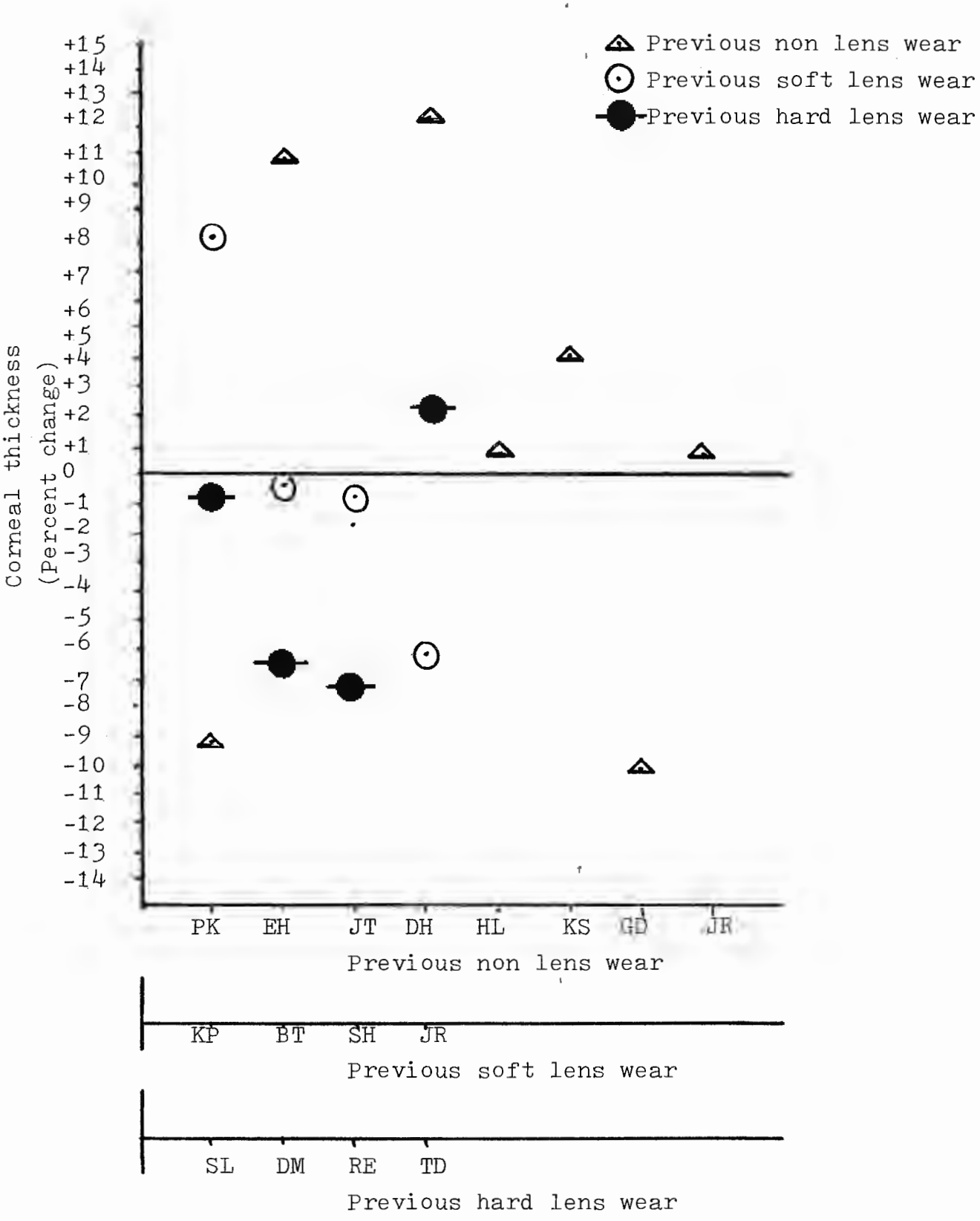
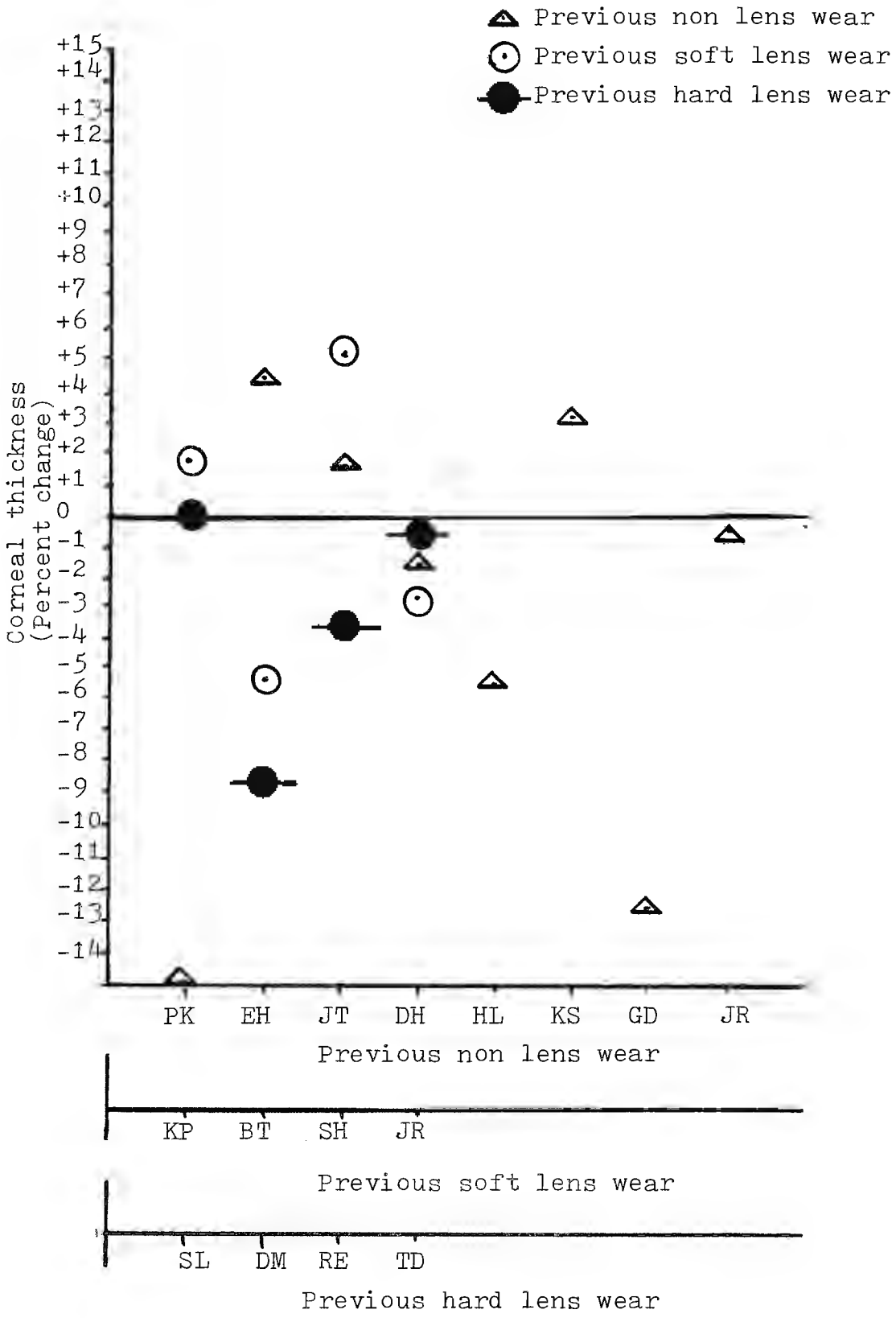


Figure 14 Individual percent change for central corneal thickness between baseline and 28 days of GP II wear.



APPENDIX A

POLYCON(R) II (silafocon A) CONTACT LENSES

9.0 DIAMETER SPECIFICATIONS

Lens Diameter	9.0mm
Optic Zone Diameter	7.8mm
Secondary Curve Width	0.40mm
Peripheral Curve Width	0.20mm

BASE CURVE	SECONDARY CURVE	PERIPHERAL CURVE
7.00	7.90	9.70
7.05	7.90	9.80
7.10	8.00	9.90
7.15	8.10	10.10
7.20	8.10	10.20
7.25	8.20	10.30
7.30	8.30	10.40
7.35	8.30	10.60
7.40	8.40	10.70
7.45	8.50	10.80
7.50	8.60	10.90
7.55	8.60	11.10
7.60	8.70	11.20
7.65	8.80	11.30
7.70	8.80	11.50
7.75	8.90	11.60
7.80	9.00	11.70
7.85	9.10	11.90
7.90	9.10	12.00
7.95	9.20	12.20
8.00	9.30	12.30
8.05	9.30	12.40
8.10	9.40	12.60
8.15	9.50	12.70
8.20	9.60	12.90
8.25	9.60	13.00
8.30	9.70	13.20
8.35	9.80	13.30
8.40	9.90	13.50
8.45	9.90	13.60
8.50	10.00	13.80
8.55	10.10	13.90
8.60	10.20	14.10

APPENDIX B

GPII LENSES

CAB FINISHING CURVES

BASE CURVE	PERIPHERAL CURVE	SECONDARY CURVE AND BLEND
41.00	13.0	9.45
41.25 - 42.25	13.0	9.20
42.50 - 43.50	12.5	8.95
43.75 - 45.00	12.5	8.70
45.25 - 46.00	12.0	8.45

CURVE WIDTHS

DIA.	O.Z.	P.P.C.	P.S.C.	BLEND
9.2	7.6	.4	.2	.2
8.8	7.2	.4	.2	.2
9.6	8.0	.4	.2	.2

The edge thickness for all our lenses -1.00 to 6.00 is calculated to .08 finished edge thickness.

Center thickness for all minus lenses is .18 mm.

APPENDIX C

1. Institution

A.	Title of Project:	A Clinical Comparison of Two Gas Permeable Contact Lenses (Polycon II and GPII) with Respect to Corneal Edema.
B.	Principal Investigators:	Nick Shashati (357-5346) and Mitch Harstad (357-7220)
C.	Advisor:	Dr. Donald West
D.	Location:	Pacific University College of Optometry, Forest Grove, Oregon
E.	Date:	1983

2. Description of Project

This project is designed primarily to compare the corneal edema (swelling) produced by two newly FDA approved contact lenses, Polycon II and GPII. Pachometric measurements and biomicroscopy observations will be used to assess corneal edema. (Pachometry is a method of measuring the thickness of the cornea).*

3. Description of Risks

There are a number of normal adaptive symptoms which may occur upon installation of any contact lens. These include: itching, tearing, photophobia, corneal swelling, and intermittent blurred vision. These are normal first-time contact lens symptoms and they will subside upon adaptation to the lenses. Also, after removing the contact lenses patients may notice that their spectacle correction is not satisfactory. If this occurs, notify the investigators and avoid dangerous and demanding tasks such as driving. The risks are minimal and the same as if you were fitted with regular contact lenses. If any problems occur please contact Nick Shashati (357-5346), Mitch Harstad (357-7220), or Dr. Donald West (357-6151, Ext. 284). If you are still not satisfied, contact Dr. James Peterson (357-0442).

4. Description of Benefits

This study will serve as a comparative study between Polycon II and GPII lenses. **The contact lenses, diagnostic exam, progress exams, and modifications up to 4 weeks after initial fit will be provided at no cost to patient.**

5. Compensation and Medical Care

If you are injured in this experiment it is possible that you will not receive compensation or medical care from Pacific University, the experimenters, or any organization associated with the experiment. However, all reasonable care will be used to prevent injury.

6. Alternatives Advantageous to Subjects

Not applicable.

7. Offer to Answer any Inquiries

The experimenters will be happy to answer any questions that you may have at any time during the course of this study.

8. Freedom to Withdraw

You are free to withdraw your consent and to discontinue participation in this project or activity at any time without prejudice to you.

* This is done optically--solely by light reflection.

** **Thereafter, any contact lens service will be covered under general clinic fee policy at patient's own expence.**

I have read and understand the preceeding information. I am 18 years of age or over.

Printed Name _____

Signed _____

Address _____ Date _____

_____ Phone _____

Name and address of a person not living with you who will always know your address

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